39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	JC-1	
Committee:	Liaison	
New Procedure		
Procedure Change		
Const./Bylaws Change		

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

A. Summary of Proposal

To provide clarity for Item 15r DRUG AND CHEMICAL STORAGE requirements and administrative procedures with respect to homeopathic/all natural drugs, medical products, and drugs (active ingredient) which pre-date the Federal Food, Drug, and Cosmetic Act.

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

For more than a decade, the dairy industry has requested that FDA take action to restrict availability to the proliferation of homeopathic/all natural drugs, medical products, and other drugs which pre-date the Federal Food, Drug, and Cosmetic Act that have not been approved by FDA but are marketed for use in dairy cattle. Due to FDA inaction, there are numerous products available today with label indications and marketing claims for treatment of various diseases and infection causing organisms or to treat symptoms such as fever and pain. In essence, FDA is openly allowing these products in the marketplace to be targeted for sale to dairy farmers.

This places dairy farmers as the regulatory force to determine which products are legal to use on their animals. Dairy farmers are not equipped to make these determinations and rightfully believe that these products are legal to use because the FDA has taken no regulatory action against manufactures to remove these products from the marketplace. However, FDA requires

inspectors to make a 5-point deduction when any of these of homeopathic/all natural drugs, medical products, and other drugs (active ingredient) which pre-date the Federal Food, Drug, and Cosmetic Act that have not been approved by FDA but are marketed for use in dairy cattle are found on a farm. Dairy farmers are being penalized because FDA is not taking regulatory enforcement action against the manufacturers.

This proposal provides clarity for Item 15r DRUG AND CHEMICAL STORAGE requirements and administrative procedures with respect to homeopathic/all natural drugs, medical products, and drugs (active ingredient) which pre-date the Federal Food, Drug, and Cosmetic Act. For any of these products for which FDA has taken no regulatory enforcement action against the manufacturer, it will be noted on the inspection form but no points on state ratings and check ratings for Item 15r will be deducted.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
Section 7 Item 15r, page 56-57	**2023 PMO** ***Section(s):* 7** ***Appendix:***		**2023 EML**
	2023 MMSR		**Forms** ***Form Number:***
	2023 Procedures		**2023 Constitution and Bylaws**

Proposed Change:

This Item is deemed to be satisfied when:
1. Cleaners and sanitizers, used on dairy farms, shall be purchased in containers from the manufacturer or distributor, which properly identify the contents or, if bulk cleaners and sanitizers are transferred from the manufacturer's or distributor's container, that the transfer only occurs into a dedicated end-use container, which is specifically designed and maintained according to the manufacturer's specifications for that specific product. The label on the dedicated end-use container shall include the product name, chemical description, use directions, precautionary and warning statement, first aid instructions, container storage and maintenance instructions and the name and address of the manufacturer or distributor.
2. Equipment used to administer drugs is not cleaned in the wash vats and is stored so as not to contaminate the milk or milk-contact surfaces of equipment.
3. Drugs intended for the treatment of non-lactating dairy animals are segregated from those drugs used for lactating dairy animals. Separate shelves in cabinets, refrigerators or other storage facilities satisfy this Item.
4. Drugs shall be properly labeled to include the name and address of the manufacturer or distributor for over-the-counter (OTC) drugs, or veterinary practitioner dispensing the product for prescription (Rx) and extra-label use (ELU) drugs. Drug labels shall include:

a. Name and address of the prescribing veterinarian. If the drug is dispensed by a pharmacy on the order of a veterinarian, the labeling shall include the name of the prescribing veterinarian and the name and address of the dispensing pharmacy and may include the address of the prescribing veterinarian.

b. Name of the active ingredient(s). This requirement is met by displaying the drug's common, generic, scientific, or chemical name. Listing of a trade or brand name is not acceptable.

c. Adequate directions for use: including any directions for use specified by the veterinarian, including the class/species or identification of the animal being treated, for which the drug is intended to be used; the dosage, frequency, and route of administration; and the duration of therapy.

d. Withholding times for meat and discard time for milk, even if zero. e. Any necessary cautionary statements.

5. Drugs which are capable of acting systemically and causing violative residues, which are not approved by FDA regardless of the route of administration, cannot be used or stored on the dairy operation. Unapproved, improperly labeled and/or drugs listed in 21 CFR 530.41 as prohibited for extra-label use are not used to treat dairy animals and are not stored in the milkhouse, milking barn, stable or parlor (includes homeopathic/all-natural type drugs, medical products, and drugs (active ingredient) which pre-date the FFD&CA*).

6. Drugs are stored in such a manner that they cannot contaminate the milk or milk product-contact surfaces of the containers, utensils or equipment.

7. With regard to drug storage, labeling and use, the scope of a dairy operation/inspectional area extends beyond the milkhouse, milking barn or parlor. The following areas are part of the milking operation: any area reasonably expected to contain drugs used to treat lactating and non-lactating animals. Private residences and vehicles are not included without the permission of the owner or their authorized agent.

8. Only a veterinarian may prescribe an FDA approved animal or human drug for extra-label purposes. Such ELU of drugs by veterinarians is provided for under the parameters in the Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994 and Title 21 Code of Federal Regulations, Part 530 (21 CFR 530). All ELU drugs must be labeled to comply with AMDUCA and Item 15r of the PMO.

9. Ovarian (estrogens and progesterone) and adrenalin (epinephrine) hormones are not exempted from the PMO drug labeling and storage requirements. Such products shall be properly labeled by a veterinarian or pharmacist.

10. Foot baths and sprays that contain antibiotics must be operated in a manner that will not contaminate the milk or milk product contact surfaces of the milking equipment.

11. Medicated feeds or blocks intended for non-lactating dairy animals shall be segregated from medicated feeds or blocks for lactating dairy animals and must be stored in a manner that is inaccessible to lactating dairy animals.

NOTE: Topical antiseptics and wound dressings, unless intended for direct injection into the teat, vaccines and other biologics, and dosage form vitamins and/or mineral products are exempt from labeling and storage requirements, except when it is determined that they are stored in such a manner that they may contaminate the milk or milk product-contact surfaces of containers, utensils or equipment applied topically for a systemic effect or intended for direct injection into the teat. Topically applied drugs that are not antiseptics or wound dressings must comply with all labeling, use and storage requirements of this item.

* Homeopathic/all natural drugs, medical products, and drugs (active ingredient) which pre-date the FFD&CA must comply with the FFD&CA as well as the drug labeling and storage requirements of the PMO. If FDA has taken enforcement action against the manufacturer of these products and they do not comply with the drug labeling requirements, they are addressed on dairy farm inspections like other unapproved drugs. For any of these products for which the FDA has taken no enforcement action against the manufacturer, it will be noted on the inspection form but no points on state ratings and check ratings for Item 15r will be deducted.

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39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	JC-2	
Committee:	Other Species/ Scientific/ MMSR/ ICP	
New Procedure		
Procedure Change		
Const./Bylaws Change		

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

A. Summary of Proposal

This proposal will update Section 8. Animal Health to reference current federal regulatory disease documents and align the corresponding portions of the PMO and MMSR.

It also removes prescriptive disease testing requirements in lieu of broader statements regarding animal health and disease surveillance. It more accurately references state animal health officials and federal USDA APHIS Veterinary Services for specific regulatory disease testing.

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

Healthy dairy animals are critical to providing safe and wholesome Grade "A" products. However, oversight for specific regulatory animal disease testing programs of dairy animals should be conducted by the agencies with existing regulatory authority to ensure compliance and take appropriate regulatory actions.

The goal of this proposal is to replace the prescriptive testing requirements for tuberculosis and brucellosis with a One Health-focused approach. The proposal reflects current regulatory disease surveillance programs, and maintains primary animal health decisions for those diseases under the authority of the State Animal Health Official and USDA APHIS Veterinary Services.

States continue to work with USDA and other partners to prevent, detect, and respond to cases of brucellosis or tuberculosis in domestic livestock. Surveillance may be done at slaughter, pre-movement testing, or voluntary certification programs, depending on the species and state status. Surveillance programs may be state-specific but must meet USDA standards for demonstrating disease-free status and for interstate movement.

Sheep, goats, and camelids are not included in 9 CFR Part 77 Tuberculosis, or in the USDA Bovine Tuberculosis Eradication Uniform Methods and Rules (effective January 1, 2005). Neither does 9 CFR Part 78 Brucellosis nor USDA Brucellosis Eradication: Uniform Methods and Rules, Effective October 1, 2003 reference sheep, goats, or camelids. Because these species are not specifically addressed in these regulatory documents, the PMO has traditionally included prescriptive testing requirements for these species in Section 8 for brucellosis and tuberculosis. Given the low risk, and continued surveillance through other mechanisms, a broader approach is appropriate.

This proposal maintains the intent of previous versions of Section 8 while taking a broader, more flexible approach. It allows animal health agencies to address specific animal disease testing, while allowing the PMO to maintain authority of the milk safety from those animals.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
124-127; 134; 136-137	**2023 PMO** ***Section(s):* 8, 15, & Footnotes** ***Appendix: A***		**2023 EML**
99-100	**2023 MMSR**		**Forms** ***Form Number:***
	2023 Procedures		**2023 Constitution and Bylaws**

Proposed Changes:

PMO Section 8 pages 124-127

SECTION 8. ANIMAL HEALTH

Healthy dairy animals are critical to providing safe and wholesome Grade "A" products.

PUBLIC HEALTH REASON

The health of the animal is a very important consideration, because a number of diseases, including tuberculosis, brucellosis, Q-fever, salmonellosis, staphylococcal infection and streptococci infection, may be transmitted to man through the medium of milk. The organisms of most of these diseases may get into the milk either directly from the udder, or indirectly through infected body discharges which may drop, splash or be blown into the milk.

The great reduction in the incidence of bovine tuberculosis in man indicates that the practice of good sanitation in animal husbandry, the testing of dairy animals and removal of the reactors from the herds, and the pasteurization of milk, have been effective in the control of this disease. The reservoir of bovine tuberculosis still exists; however, constant vigilance against this disease must be continued by industry and Regulatory Agencies.

ADMINISTRATIVE PROCEDURES

1. All milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging shall be from herds ~~under a tuberculosis eradication program,~~ which ~~meets~~ meet one (1) of the following conditions:
a. Areas which have Modified Accredited Advanced Tuberculosis (TB) status or higher as determined by the USDA; or
b. An Area which fails to maintain such status:
(1) Any herd shall have been accredited by USDA; or
(2) Shall have passed an annual tuberculosis test; or
(3) The Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and the Regulatory Agency.

NOTE: Under the Federal USDA Bovine Tuberculosis Eradication Program, only cattle, bison and captive cervids are covered under the USDA State tuberculosis status determination. Therefore, other hooved mammals (goats, sheep, water buffalo, camels, etc.) are not covered within the program and shall comply with ~~one (1) of the options cited under~~ Item 3 below.

NOTE: For the ICP, an official letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation or recertification, or certificate identifying the animals tested, the date of injection, the date of the reading of the test and the results of the test signed by the State, Provincial, or Country's Veterinary or Public Health Services shall be provided as directed by the TPC.

2. All milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging shall be from herds ~~under a brucellosis eradication program,~~ which ~~meets~~ meet one (1) of the following conditions:
a. Located in a Certified Brucellosis-Free Area as defined by USDA ~~and enrolled in the testing program for such areas~~; or
b. Meet USDA requirements for a Certified Brucellosis-Free Herd; or

~~c. Participating in a milk ring testing program at least two (2) times per year at approximately one hundred eighty (180) day intervals and all herds with positive milk ring results shall have the entire herd blood tested within thirty (30) days from the date of the laboratory ring tests; or~~
c. Shall have established a brucellosis testing protocol for livestock that assures brucellosis protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and the Regulatory Agency.
~~d. Have an individual blood agglutination test on all cattle or bison six (6) months of age or older, except steers and spayed heifers, annually with an allowable maximum grace period not exceeding two (2) months.~~

NOTE: For the ICP, a certificate identifying each animal signed by the State, Provincial, or Country's Veterinary or Public Health Services and director of the laboratory conducting the testing, shall be provided as directed by the TPC.

NOTE: Under the Federal USDA Bovine Brucellosis Eradication Program, only cattle and bison are covered under the USDA State brucellosis status determination. Therefore, cattle are the only dairy animal currently covered by both the Federal USDA brucellosis and tuberculosis programs. All other hooved mammals (goats, sheep, water buffalo, camels, etc.) are not covered within these programs and shall comply with ~~one (1) of the options cited under~~ Item 3 below.

3. Goat, sheep, water buffalo, camel, or any other hooved mammal milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging, defined under this *Ordinance*, shall be from a herd or flock that~~:~~
~~a. Has passed an annual whole herd or flock brucellosis and/or tuberculosis testing as recommended by the State Veterinarian or USDA Area Veterinarian in Charge (AVIC) using tests approved by USDA APHIS for the specific disease and species (blood testing for brucellosis and the caudal fold tuberculin test for tuberculosis); or~~
~~b. Has passed an initial whole herd brucellosis and/or tuberculosis testing, followed only by testing replacement animals or any animals entering the milking group or sold as dairy animals using tests approved by USDA APHIS for the specific disease and species (blood testing for brucellosis and the caudal fold tuberculin test for tuberculosis); or~~
~~c. Has passed an annual random individual animal brucellosis and/or tuberculosis testing program, using tests approved by USDA APHIS for the specific disease and species (blood testing for brucellosis and the caudal fold tuberculin test for tuberculosis), sufficient to provide a confidence level of 99% with a P value of 0.05. Any herd or flock with one (1) or more confirmed positive animals shall go to 100% testing until the whole herd tests show no positive animals are found; or~~
~~d. Has passed a USDA APHIS approved bulk milk test for the specific disease and species, at USDA APHIS recommended frequency, with an implementation date based on the availability of the bulk milk test once USDA APHIS has approved such a test for the specific disease and species~~

~~(The brucellosis ring test is USDA-APHIS-approved for the bovine species and is not suitable for most non-bovine species.); or~~

~~e Is~~ is determined to be free of brucellosis and/or tuberculosis as provided by the development and implementation of a State administered brucellosis-free and/or tuberculosis-free ~~herd~~ certification program involving a documented surveillance program~~, which includes records supporting the tests required in this Section,~~ and an official ~~annual~~ written certification from the State Veterinarian documenting their brucellosis-free and/or tuberculosis-free status. The surveillance program shall be documented and the official ~~annual~~ written State brucellosis-free and/or tuberculosis-free certification shall be retained on file with the State Regulatory Agency. ~~This official annual written State brucellosis-free and/or tuberculosis-free certification shall include a current list of Grade "A" non-cattle dairy herds and/or flocks (goats, sheep, water buffalo, camels, etc.) that are covered within the documented surveillance program and contained within the official annual written State brucellosis-free and/or tuberculosis-free certification.~~

(Refer to the **NOTE** on page 31.)

~~The following table[14] will provide the random sampling size needed to achieve 99% confidence with a P-value of 0.05:~~

~~**Herd/Flock Size**~~	~~**Sampling Size**~~	~~**Herd/Flock Size**~~	~~**Sampling Size**~~
~~20~~	~~20~~	~~500~~	~~82~~
~~50~~	~~41~~	~~600~~	~~83~~
~~100~~	~~59~~	~~700~~	~~84~~
~~150~~	~~67~~	~~800~~	~~85~~
~~200~~	~~72~~	~~1000~~	~~86~~
~~250~~	~~75~~	~~1400~~	~~87~~
~~300~~	~~77~~	~~1800~~	~~88~~
~~350~~	~~79~~	~~4000~~	~~89~~
~~400~~	~~80~~	~~10000~~	~~89~~
~~450~~	~~81~~	~~100000~~	~~90~~

4. For diseases other than brucellosis and tuberculosis, the Regulatory Agency shall require such physical, chemical or ~~bacteriological~~ microbiological tests, as it deems necessary. The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed and accredited~~[15]~~[14] veterinarian or an accredited veterinarian in the employ of an official Agency. Any diseased animal disclosed by such test(s) shall be disposed of as the Regulatory Agency directs.

~~5. Records supporting the tests required in this Section shall be available to the Regulatory Agency and be validated with the signature of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official Agency.~~

NOTE: For the ICP, references to USDA and/or State in Items 1 through ~~5~~ 4 above, shall mean the Government Agency responsible for animal disease control in the Country or region of that Country. The term "accredited veterinarian" shall mean an individual veterinarian authorized for those activities in said Country or region of that Country.

PUBLIC HEALTH REASON

The health of the animal is a very important consideration, because a number of diseases of cattle, including tuberculosis, brucellosis, Q fever, salmonellosis, staphylococcal infection and streptococci infection, may be transmitted to man through the medium of milk. The organisms of most of these diseases may get into the milk either directly from the udder, or indirectly through infected body discharges which may drop, splash or be blown into the milk.
The great reduction in the incidence of bovine tuberculosis in man indicates that the practice of good sanitation in animal husbandry, the testing of dairy animals and removal of the reactors from the herds, and the pasteurization of milk, have been effective in the control of this disease. The reservoir of bovine tuberculosis still exists; however, constant vigilance against this disease must be continued by industry and Regulatory Agencies.

ADMINISTRATIVE PROCEDURES

BOVINE TUBERCULOSIS: All tuberculosis tests and retests response activities shall be made, and any reactors disposed of, in accordance with the current edition of *Uniform Methods and Rules; Bovine Tuberculosis Eradication*, *Uniform Methods and Rules for Establishment and Maintenance of Tuberculosis-Free Accredited Herds of Cattle*, *Modified Accredited Areas and Areas Accredited Free of Bovine Tuberculosis in the Domestic Bovine*, as published by USDA .
For tuberculosis test purposes, the herd is defined as all adult cattle twenty-four (24) months of age and over, including any commingled beef animals. Dairy cattle less than two (2) years of age and already milking shall be included in the herd test. A letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation, or a certificate identifying the animals tested, the date of injection, the date of reading of the test and the results of the test signed by a USDA accredited veterinarian, shall be evidence of compliance with the above requirements and shall be filed with the Regulatory Agency. (Refer to Appendix A. of this *Ordinance*.)

NOTE: For the ICP, an official letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation or recertification, or certificate identifying the animals tested, the date of injection, the date of the reading of the test and the results of the test signed by the Country's Veterinary Services shall be provided as directed by the TPC.

BOVINE BRUCELLOSIS: All brucellosis tests, retests, disposal of reactors, vaccination of calves and certification of herds and areas shall be in accordance with the current edition of *Brucellosis Eradication*, *Recommended Uniform Methods and Rules*, as published by USDA. All reactors disclosed on blood agglutination tests shall be separated immediately from the milking herd and the milk of these reactors shall not be used for human consumption.
A certificate identifying each animal, signed by the veterinarian and the director of the laboratory making the test, shall be filed as directed by the Regulatory Agency. Provided, that in the event the herd is subject to the milk ring test, the record shall be required to show only the date and results of such test. Within thirty (30) days following the expiration of an official milk ring testing program, or in the case of a herd subject to annual blood tests, thirteen (13) months following the last annual blood tests, the Regulatory Agency shall notify the herd owner or operator of the necessity to comply with the brucellosis requirements. The failure of the herd owner or operator to comply with the brucellosis requirements within thirty (30) days of written notice shall result in immediate suspension of the permit. (Refer to Appendix A. of this *Ordinance*)

~~**NOTE:** For the ICP, a certificate identifying each animal signed by the Country's Veterinary Services and director of the laboratory conducting the testing, shall be provided as directed by the TPC.~~

PMO Section 15 Enforcement page 134

This *Ordinance* shall be enforced by the Regulatory Agency in accordance with the *Grade "A" PMO*, with **ADMINISTRATIVE PROCEDURES**, current edition. A certified copy~~16~~ 15 of which shall be on file at the appropriate Regulatory Agency's office. Where the mandatory compliance with provisions of the Appendixes is specified, such provisions shall be deemed a requirement of this *Ordinance*.

PMO FOOTNOTES page 136

~~14. From Table 1, Regulatory Statistics, 5th Edition (June 1975) by Victor C. Beal, Jr., Programs Development and Application, Veterinary Services, APHIS: Animal Health Programs.~~

~~15~~ 14. The term "accredited" in this Section means accredited by the USDA APHIS Veterinary Services.

~~16~~ 15. A certified copy may be secured from the Food and Drug Administration, HFS-316, 5001 Campus Drive, College Park, MD 20740-3835.

NOTE: In reference to Footnotes 2, 7, 8, 9, 10, 11, 12, and 13, for the purposes of the ICP, cottage cheese, dry curd cottage cheese and reduced fat or low-fat cottage cheese shall be Grade "A" and shall be regulated under the terms of this *Ordinance*.

PMO Appendix A page 137

APPENDIX A. ANIMAL DISEASE CONTROL

Copies of the *Bovine Tuberculosis Eradication: Uniform Methods and Rules (available at* https://www.aphis.usda.gov/animalhealth/animaldiseases/tuberculosis/downloads/tb-umr.pdf*)* and *Brucellosis Eradication: Uniform Methods and Rules, (available at* ~~*https://www.aphis.usda.gov/sites/default/files/umr-bovine-bruc.pdf*~~ *www.aphis.usda.gov/sites/default/files/umr_bovine_bruc.pdf),* current at the time of the adoption of this *Ordinance* are available electronically using the hyperlinks above or may be obtained from your State Veterinarian or:

Veterinary Services
Animal and Plant Health Inspection Service (APHIS)
U. S. Department of Agriculture 4700 River Road, Unit 43
Riverdale, MD 20737

http://www.aphis.usda.gov/animal health/ Or

Federal Area Veterinarian in Charge
Veterinary Services, APHIS, USDA
Your State Capitol

It is recommended that Regulatory Agencies initiate and/or promote a mastitis control program. A well-planned and extended educational phase will encourage the support of producers and reduce the problems of enforcement.
The National Mastitis Council (NMC), 421 S. Nine Mound Road, Verona, WI 53593 (www. nmconline.org), has studied a large number of existing control programs and has outlined a suggested flexible control program. In addition, review of the current knowledge of mastitis may be found in their publications: *Current Concepts of Bovine Mastitis* and the *Laboratory Handbook of Bovine Mastitis.*
Sanitarians may find the screening test a useful device for detecting abnormal milk. Sample screening methods, as well as somatic cell diagnosis and reduction programs are discussed in the references above as well as the Dairy Practices Council (DPC), ~~708 Sherman Street, Pandora, OH 45877~~ P.O. Box 673, Monroe, ME 04951 (https://www.dairypc.org/) publication: *The Fieldperson's Guide to Troubleshooting High Somatic Cell Counts,* DPC Guide Number 18.
Regulatory action should not be based on the use of mastitis screening tests alone. Screening tests should be used as an adjunct to a complete program of mastitis control and milking-time inspections.

MMSR Appendix A Dairy Farms-Part 1 pages 99-100

5. Tuberculosis (TB) and Brucellosis Certification on file as required (*Grade "A" PMO,* Section 8. ANIMAL HEALTH and Appendix A. Animal Disease Control). All or nothing Item based on record verification.

a. Located in an area that has a Modified Accredited Advance TB status or higher as determined by USDA; or

An area which fails to maintain such status:

1.) Any herd shall have been accredited by USDA; or
2.) Shall have passed an annual TB test; or
3.) The Area shall have established a TB testing protocol for livestock that assures TB protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and the Regulatory Agency.

NOTE: Under the Federal USDA Bovine Tuberculosis Eradication Program, only cattle, bison and captive cervids are covered under the USDA State tuberculosis status determination. Therefore, other hooved mammals (goats, sheep, water buffalo, camels, etc.) are not covered within the program and shall comply with ~~one (1) of the options cited under~~ Item c. below.

b. Located in a Certified Brucellosis-Free Area as defined by USDA and enrolled in the testing program for such areas; or

1.) Meet USDA requirements for a Certified Brucellosis-Free Herd; or
~~2.) Participate in a milk ring testing program at least two (2) times per year at approximately one hundred eighty (180) day intervals and all herds with positive milk ring results shall have the entire herd blood tested within thirty (30) days from the date of the laboratory ring tests; or~~
~~3.) Have an individual blood agglutination test on all cattle or bison six (6) months of age or older, except steers and spayed heifers, annually with an allowable maximum grace period not exceeding two (2) months.~~

2.) Have established a brucellosis testing protocol for livestock that assures brucellosis protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and the Regulatory Agency.

NOTE: Under the Federal USDA Bovine Brucellosis Eradication Program, only cattle and bison are covered under the USDA State brucellosis status determination. Therefore, cattle are the only dairy animal currently covered by both the Federal USDA brucellosis and tuberculosis programs. All other hooved mammals (goats, sheep, water buffalo, camels, etc.) are not covered within these programs and shall comply with ~~one (1) of the options cited under~~ Item c. below.

c. Goat, sheep, water buffalo, camel or any other hooved mammal, excluding cattle and bison, shall be from a herd or flock that~~:~~

~~1.) Has passed an annual whole herd or flock brucellosis and/or tuberculosis testing as recommended by the State Veterinarian or USDA Area Veterinarian in Charge (AVIC) using tests approved by USDA APHIS for the specific disease and species (blood testing for brucellosis and the caudal fold tuberculin test for tuberculosis); or~~

~~2.) Has passed an initial whole herd brucellosis and/or tuberculosis testing, followed only by testing replacement animals or any animals entering the milking group or sold as dairy animals using tests approved by USDA APHIS for the specific disease and species (blood testing for brucellosis and the caudal fold tuberculin test for tuberculosis); or~~

~~3.) Has passed an annual random individual animal brucellosis and/or tuberculosis testing program, using tests approved by USDA APHIS for the specific disease and species (blood testing for brucellosis and the caudal fold tuberculin test for tuberculosis), sufficient to provide a confidence level of 99% with a P value of 0.05. Any herd or flock with one (1) or more confirmed positive animals shall go to 100% testing until the whole herd tests show no positive animals are found; or~~

~~4.) Has passed a USDA APHIS approved bulk milk test for the specific disease and species, at UDSA APHIS recommended frequency, with an implementation date based on the availability of the bulk milk test once USDA APHIS has approved such a test for the specific disease and species (The brucellosis ring test is USDA APHIS approved for the bovine species and is not suitable for most non-bovine species.); or~~

~~5 Is~~ is determined to be free of brucellosis and/or tuberculosis as provided by the development and implementation of a State administered brucellosis-free and/or tuberculosis-free ~~herd~~ certification program involving a documented surveillance program~~, which includes records supporting the tests required in this Section,~~ and an official ~~annual~~ written certification from the State Veterinarian documenting their brucellosis-free and/or tuberculosis-free status. The surveillance program shall be documented and the official ~~annual~~ written State brucellosis-free and/or tuberculosis-free certification shall be retained on file with the State Regulatory Agency. ~~This official annual written State brucellosis-free and/or tuberculosis-free certification shall include a current list of Grade "A" non-cattle dairy herds and/or flocks (goats, sheep, water buffalo, camels, etc.) that are covered within the documented surveillance program and contained within the official annual written State brucellosis-free and/or tuberculosis-free certification.~~

d. Tuberculosis and/or Brucellosis certificates on file as required by the Regulatory Agency.
e. Notice of status changes readily available to the Regulatory Agency.
f. Milk from Brucellosis reactor animals withheld as required.

NOTE: For the ICP, references to USDA and/or State within 5 above, shall mean the Government Agency responsible for animal disease control in the Country or region of that Country. The term

"State Veterinarian" shall mean an individual veterinarian authorized for those activities in said Country or region of that Country.

Name:	Other Species Committee (Bradley Turpin – Chair)		
Agency/Organization:	Colorado Department of Public Health & Environment		
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39th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	JC-3	
Committee:	Lab, ICP	
New Procedure		
Procedure Change		
Const./Bylaws Change		

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

A. Summary of Proposal

To allow Third Party Certifiers to use Proficiency Test Providers that follow the protocols outlined in the EML (referenced in the current edition of International Standards Organization (ISO) 17043, ISO 13528 and/or the International Harmonized for the Proficiency Testing of Analytical Chemistry Laboratories) to provide Proficiency Samples to the laboratories under their oversight.

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

With the changes that have occurred in the shipping industry, it has become impossible to get Split Samples produced by an IMS recognized Milk Laboratory Control Agency to laboratories approved in other countries under the International Certification Program. There are Proficiency Test Providers in these countries that follow the protocols referenced in the current edition of International Standards Organization (ISO) 17043, ISO 13528 and/or the International Harmonized for the Proficiency Testing of Analytical Chemistry Laboratories. These are the same standards that are now referenced in the EML and would enable these labs to resume participation in Proficiency Testing.

C. Proposed Solution

Changes to be made on the following NCIMS Documents:

Page Number(s)	Document	Page Numbers(s)	Document
	2023 PMO ***Section(s):*** ***Appendix:***	13	**2023 EML**
	2023 MMSR		**Forms** ***Form Number:***
	2023 Procedures		**2023 Constitution and Bylaws**

Proposed Change:

EML Section 3 Page 13

Milk Laboratory Control Agencies having less than ten (10) analysts (total) in their milk laboratory program are to develop joint proficiency testing programs with other Milk Laboratory Control Agencies that can meet the criteria for certification of analysts and accreditation of laboratories. In cases where a minimum number of analysts (≥ 10) is not available, evaluation of proficiency shall be made by a determination that the LEO and the FDA/LPET agree is appropriate.

Third Party Certifiers who are unable to obtain proficiency test samples from another Milk Laboratory Control Agency for the laboratories under their oversight are to find a Proficiency Test Provider following the protocols referenced in the current edition of International Standards Organization (ISO) 17043, ISO 13528 and/or the International Harmonized for the Proficiency Testing of Analytical Chemistry Laboratories to provide Proficiency Samples to the laboratories under their oversight.

An acceptable annual proficiency testing program shall meet the following applicable criteria:

Name: Laura Traas

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