ADMINISTRATIVE CODE

CHAPTER 420-3-16-A
APPENDICES

420-3-16-AN Appendix N - Drug Residue Teting and Farm Surveillance.

I. INDUSTRY RESPONSIBILITIES MONITORING AND SURVEILLANCE

Industry shall screen all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, regardless of final use, for Beta lactam drug residues. Additionally, other drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers when the Commissioner of the FDA determines that a potential problem exists as cited in Rule 420-3-16-.07. The random bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers sampling program shall represent and include, during any consecutive six (6) months, at least four (4) samples collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. Samples collected under this random sampling program shall be analyzed as specified by the FDA (refer to Rule 420-3-16-.07).

The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. These bulk milk pickup tanker samples may be collected using an approved aseptic sampler. The sample shall be representative. Bulk milk pickup tanker testing shall be completed prior to processing the milk. Bulk milk pickup tanker samples confirmed positive for drug residues using approved test methods and/or verified screening positive using test methods not evaluated by the FDA and accepted by the NCIMS without additional confirmation required shall be retained as determined necessary by the Health Officer.

All raw milk supplies that have not been transported in bulk milk pickup tankers shall be sampled prior to processing the milk. The sample(s) shall be representative of each farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. Testing of all raw milk supplies that have not been transported in bulk milk pickup tankers shall be completed prior to processing the milk.

Note: On-farm producer/processors that plan to store or ship their raw sheep milk frozen shall sample their raw sheep milk prior to freezing. The sample shall be obtained by a bulk milk hauler or sampler permitted by the Health Officer where the dairy farm is located. The raw sheep milk sample shall then be tested in a certified laboratory or screening facility. If this is the on-farm producer/processor's only raw sheep milk supply, this testing would suffice for the required Appendix N testing for all raw milk supplies that have not been transported in bulk milk pickup tankers, which are required to be completed prior to processing the milk. In the case of sheep milk dairy farms, the raw milk sample may be frozen in accordance with a sample protocol approved by the Health Officer in which the dairy farm is located as specified in Appendix B and transported to a certified laboratory for testing. The test results, or raw milk samples, shall clearly distinguish the lot number of the frozen raw sheep milk and accompany the frozen raw sheep milk to the plant.

All presumptive positive test results for drug residues using approved test methods or verified screening positive test results using test methods not evaluated by the FDA and accepted by the NCIMS from analysis conducted on commingled raw milk tanks, bulk milk pickup tankers, and/or all raw milk supplies that have not been transported in bulk milk pickup tankers or farm raw milk tanks/silos (only milk offered for sale) samples shall be reported to the regulatory agency in which the testing was conducted. Bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers samples confirmed positive for drug residues using approved test methods or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be retained or disposed of as determined by the regulatory agency.

Industry plant samplers shall be evaluated according to the requirements specified in Section 6 and at the frequency addressed in Section 5.

REPORTING AND FARM TRACE BACK

When a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers is found to be presumptive positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by the FDA and accepted by the NCIMS, the regulatory agency in which the testing was conducted

shall be immediately notified of the results and the ultimate disposition of the raw milk.

The producer samples from the bulk milk pickup tanker found to be confirmed positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by the FDA and accepted by the NCIMS without additional confirmation required shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the regulatory agency.

Upon official notification to the regulatory agency and milk producer of a violative individual producer's milk, further farm pickups by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer's milk shall be immediately discontinued until such time that subsequent tests are no longer positive for drug residues.

RECORD REQUIREMENTS

Results of all testing may be recorded in any format acceptable to the Health Officer that includes at least the following information:

1. Identity of the person doing the test.

2. Identity of the bulk milk pickup tanker or farm bulk milk tank(s)/ silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. used for the storage of all raw milk supplies that have not been transported in bulk milk pickup tankers being tested*.

3. Date/time the test was performed (time, day, month and year).

4. Identity of the test performed/lot #/any and all controls (+/-).

5. Results of the test.

6 Follow-up testing if the initial test was positive/any and all controls (+/-).

7. Site where test was performed.

8. Prior test documentation shall be provided for a presumptive positive load.

*Include the BTU number(s) of the dairy farms present on the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers with the above information.

Records of all sample test results shall be maintained for a minimum of six (6) months by the industry at the location where the test methods were run and/or another location as directed by the regulatory agency and as agreed to by industry. For the laboratory survey, two (2) years of records shall be available at the facility at the time of the survey.

II. REGULATORY AGENCY RESPONSIBILITIES

Upon receipt of notification from industry of a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers, which contains milk from another regulatory agency's jurisdiction, is found to be presumptive positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by the FDA and accepted by the NCIMS, it is the responsibility of the receiving regulatory agency to notify the regulatory agency(ies) from which the milk originated.

MONITORING AND SURVEILLANCE

Regulatory agencies shall monitor industry surveillance activities during either routine or unannounced on-site quarterly inspections to collect samples from bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and to review industry records of their sampling program. Samples should be collected and analyzed from at least 10 percent of the bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers scheduled to arrive on the day of the inspection. The test method used shall be appropriate for the drug being analyzed and shall be capable of detecting the same drugs at the same concentrations as the test method being used by industry. Alternately, the regulatory agency or Laboratory Evaluation Officer (LEO) may take known samples with them on the audit visit and observe the Industry Analyst (IA) test the samples. Receiving locations that choose to certify all receiving IAs certified under the provisions of the NCIMS Laboratory Certification Program are exempt from the sample collection requirements of this section. Receiving locations where all approved receiving IAs and Industry Supervisors (ISs) successfully participate in a biennial on-site evaluation and annual spilt sample comparisons by LEOs are also exempt from the sample collection requirements of this section.

A review shall include, but not be limited to, the following:

1. Is the program an appropriate routine monitoring program for the detection of drug residues?

2. Is the program utilizing appropriate test methods?

3. Is each producer's milk represented in a testing program for drug residues and tested at the frequency prescribed in Section I for drug residues?

4. Is the program assuring timely notification to the appropriate regulatory agency of positive results, the ultimate disposition of the bulk milk pickup tanker, and/or a raw milk supply that has not been transported in bulk milk pickup tankers and of the trace back to the farm of origin?

5. Is the dairy farm pickup and/or use of the violative individual producer's milk suspended until subsequent testing establishes the milk is no longer positive for drug residues?

To satisfy these requirements

a. There shall be an agreement between the Health Officer and industry that specifies how this notification is to take place. This notification shall be "timely" for example by telephone or fax, and supported in writing.

b. The ultimate disposition should either be prearranged in a documented agreement between the Health Officer and the industry, or physically supervised by the Health Officer. The milk should be disposed of in accordance with provisions of M-I-06-5 or an FDA and Health Officer reviewed and accepted specific drug residue milk diversion protocol for use as animal feed.

c. All screening test positive (confirmed) loads using an approved test method shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/ permit enforcement action) shall be performed by an Official Laboratory, Officially Designated Laboratory or Certified Industry Supervisor (CIS). Positive producers shall be handled in accordance with this appendix.

d. All verified screening test positive loads using test methods not evaluated by the FDA and accepted by the NCIMS without additional confirmation required shall be broken down (producer trace back) using the same test method. Producer trace back shall be performed as cited in a prior documented agreement with the regulatory agency (refer to Section VI). Verified screening positive producers shall be handled in accordance with this appendix.

e. All screening test positive (confirmed) loads shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed by an Official Laboratory, Officially Designated Laboratory, or Certified Industry Supervisor (CIS). Positive producers shall be handled in accordance with this appendix.

f. When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be positive (confirmed) for drug residues, the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin. Confirmation tests shall be performed by an Official Laboratory, Officially Designated Laboratory, or Certified Industry Supervisor. Positive producers shall be handled in accordance with this appendix.

g. The suspension and discontinuance of farm bulk milk tank pick up and/or the use of raw milk supplies that have not been transported in bulk milk pickup tankers is the responsibility of the industry; under the direction and supervision of the Health Officer. At the discretion of the Health Officer, records should be maintained by industry and/or the Health Officer that:

(1) Establish the identity of the producer for raw milk supplies that h pickup tankers that tested positive or the producer and the identity of the load that tested positive.

(2) Establish that milk is not picked up or used from the drug residue positive producer until the regulatory agency has fulfilled their obligations under Section II., as applicable, based on the test method utilized, and has cleared the milk for pick up and/or use.

Sufficient records should be reviewed to assure that all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers are sampled before additional commingling at the milk receiving facility and the results were made available to the appropriate BTU(s).

The Health Officer shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section 6.

ENFORCEMENT

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). The Health Officer shall determine the producer(s) responsible for the violation.

Permit Suspension and the Prevention of the Sale of Milk - Any time milk is found to test as a confirmed positive using an approved test method, the regulatory agency shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues. Upon official notification to the regulatory agency and milk producer of a confirmed positive, future farm pickups by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer's milk are prohibited until subsequent testing reveals the milk is free of drug residue.

Prevention of the Sale of Milk - Any time milk is found to test as a verified screening positive for a drug residue using test methods not evaluated by the FDA and accepted by the NCIMS without additional confirmation required, the regulatory agency shall immediately take effective measures to prevent the sale of the milk containing drug residues.

Penalties for Confirmed Positive Milk - The penalty shall be for the value of all milk on the contaminated load and/or raw milk supply that has not been transported in bulk milk pickup tankers plus any costs associated with the disposition of the contaminated load or raw milk supply that has not been transported in bulk milk pickup tankers. The regulatory agency may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.

Reinstatement - The Grade "A" producer's permit may be reinstated, or other action taken, to allow the sale of milk for human food when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.

Follow-Up - Whenever a drug residue test is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by the FDA and accepted by the NCIMS, an investigation shall be made to determine the

cause. The farm inspection is completed by the regulatory agency or its agent to determine the cause of the residue and actions taken to prevent future violations including:

1. On-farm changes in procedures necessary to prevent future occurrences as recommended by the Health Officer.

2. Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C.

Permit Revocation - After a third violation for a drug residue in a twelve (12) month period, the Health Officer shall initiate administrative procedures pursuant to the revocation of the producer's Grade "A" permit under the authority of Section 3, due to repeated violations.

HEALTH OFFICER RECORDS

In regards to the industry reporting a confirmed positive using an approved test method or verified screening positive using test methods not evaluated by the FDA and accepted by the NCIMS tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers result, the regulatory agency's records shall indicate the following:

1. What were the Health Officer's directions?

2. When was the Health Officer notified? By whom?

3. What was the identity of the load or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers?

4. What screening and/or confirmatory test(s) were used and who were the analyst(s)?

5. What was the disposition of the adulterated milk?

6. Which producer(s) was responsible?

7. Record of negative test results prior to subsequent milk pickup from the violative producer(s).

III. **TESTING PROGRAM FOR DRUG RESIDUES ESTABLISHED DEFINITIONS**

For purposes of this appendix the following definitions are to be used:

(1) **Presumptive Positive** - A presumptive positive test is a positive result from an initial testing of a bulk milk pickup tanker and/or raw milk supply that has not been

transported in bulk milk pickup tankers using an M-a-85, latest revision, or M-I-92-11 approved test method, which has been promptly repeated in duplicate with positive (+) and negative (-) controls that give the proper results using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result.

(2) Screening Test Positive (Load or Raw Milk Supply that has not been Transported in Bulk Milk Pickup Tankers Confirmation) - A screening test positive (confirmation) result is obtained when the presumptive positive sample is tested in duplicate, using the same or equivalent (M-I-96-10, latest revision) test method as that used for the presumptive positive, with a positive (+) and negative (-) control that gives the proper results, and either or both of the duplicates are positive. A screening test positive (load or farm bulk milk tank(s)/ silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers confirmation) is to be performed by an Official Laboratory, Officially Designated Laboratory or CIS using the same or an equivalent test (M-I-96-10, latest revision).

Note: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers is found to be positive (confirmed) for drug residues using approved test methods, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

(3) **Individual Producer Load** - An individual producer bulk milk pickup tanker is a bulk milk pickup tanker or a compartment(s) of a bulk milk pickup tanker that contains milk from only one (1) dairy farm.

(4) **Individual On-Farm Producer/Processor's Raw Milk Supply** - An individual on-farm producer/processor's raw milk supply may be transported in bulk milk pickup tankers; and/or their raw milk supply may be stored in a farm bulk milk tank(s)/silo(s) on the dairy farm that directly feeds the batch (vat) pasteurizer(s) or constant-level tank of a HTST pasteurization system or piped from a farm bulk milk tank(s)/silo(s) to a raw milk tank(s) and/or silo(s) in the milk plant that feeds the batch (vat) pasteurizer(s) or constant-level tank of a

HTST pasteurization system; and/or other raw milk storage containers.

(5) **Industry Analyst** - A person under the supervision of a Certified Industry Supervisor (CIS) or Industry Supervisor (IS) who is assigned to conduct screening of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for Appendix N.

(6) **Industry Supervisor/Certified Industry Supervisor** - An individual trained by a LEO who is responsible for the supervision and training of Industry Analysts (IA) who test milk tank trucks and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for Appendix N.

(7) **Certified Industry Supervisor (CIS)** - An Industry Supervisor (IS) who is evaluated and listed by a LEO as certified to conduct drug residue screening tests using approved test methods at industry drug residue screening sites for *Grade "A" PMO*, Appendix N. enforcement actions (confirmation of bulk milk pickup tankers, farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), or other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, producer trace back and/or permit actions).

(8) **Verified Screening Positive** - A verified screening positive test is a positive result from an initial testing using test methods not evaluated by the FDA and accepted by the NCIMS of a bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers, which has been promptly repeated in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result.

(9) **Producer Trace Back With Permit Suspension Action Not Required** - A producer trace back test is performed after a verified screening positive load using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required is identified by a laboratory using the same test method as was used to obtain the verified screening positive load. A verified screening positive producer test result is obtained in the same manner as a verified screening positive for a bulk milk pickup tanker. After an initial positive result is obtained on a producer sample, that sample is then tested in duplicate using the same test method as was used to obtain the initial producer positive result. This

testing is performed with positive (+) and negative (-) controls and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is a verified screening positive (refer to Section VI).

Note: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers is found to be verified screening positive for drug residues using only test methods not evaluated by the FDA and accepted by the NCIMS without additional confirmation required, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

CERTIFIED INDUSTRY SUPERVISORS; EVALUATION AND RECORDS

Reference: *EML*

1. **Certified Industry Supervisors (CISs)/Industry Supervisors (ISs)/Industry Analysts (IAs)** - Regulatory agencies may choose to allow ISs to be certified. Under this program, these CISs may officially confirm presumptive positive bulk milk pickup tanker loads and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, and confirm producer milk for regulatory purposes (producer trace back/permit action) using approved test methods. In the implementation of Appendix N, the LEO shall use the appropriate Appendix N FDA/NCIMS 2400 Form when evaluating Official Laboratories, Officially Designated Laboratories, or CISs, ISs, and IAs.

The Certified Industry Supervisor/Industry Supervisor shall report to the LEO the results of all competency evaluations performed on Industry Analysts. The names of all Certified Industry Supervisors, Industry Supervisors, and Industry Analysts, as well as their training and evaluation status, shall be maintained by the LEO and updated as replacement, additions, and/or removals occur. The LEO shall verify (document) that each Certified Industry Supervisor and/or Industry Supervisor has established a program that ensures the proficiency of the Industry Analysts they supervise. The LEO shall also verify that each Industry Supervisor and Industry Analyst has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the

LEO and the FDA Laboratory Proficiency Evaluation Team (LPET) agree is appropriate.

Failure by the Industry Supervisor or Industry Analyst to demonstrate adequate proficiency to the LEO shall lead to their removal from the LEO list of Industry Supervisors and/or Industry Analysts. Reinstatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the LEO (refer to the EML, which describes the certification requirements for Certified Industry Supervisors and the training requirements for Industry Supervisors and Industry Analysts).

2. **Sampling and Testing of Bulk Milk Pickup Tankers** - The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. The sample shall be representative. The sample analysis shall be completed before the milk is processed.

3. **Sampling and Testing of Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers** - All raw milk supplies that have not been transported in bulk milk pickup tankers shall be sampled prior to processing the milk. The sample(s) shall be representative of each farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), or other raw milk storage container(s) supply. Testing of all raw milk supplies that have not been transported in bulk milk pickup tankers shall be completed prior to processing the milk.

4. **Bulk Milk Pickup Tanker Unloaded Prior to Negative Test Result** - If the bulk milk pickup tanker is unloaded and commingled prior to obtaining a negative test result and the screening test is presumptive positive using an approved test method or verified screening positive using test methods not evaluated by the FDA and accepted by the NCIMS, the regulatory agency shall be immediately notified. If the bulk milk tanker sample is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by the FDA and accepted by the NCIMS without additional confirmation required then the commingled milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the commingled milk. The milk shall be disposed of under the supervision of the regulatory agency.

5. **Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Processed Prior to Negative Results** - If the raw milk supply that has not been

transported in bulk milk pickup tankers is processed prior to obtaining a negative test result and the screening test is presumptive positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, the regulatory agency shall be immediately notified. If the sample of the raw milk supply that has not been transported in bulk milk pickup tankers is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by the FDA and accepted by the NCIMS without additional confirmation required then the processed milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the raw milk supply and/or pasteurized milk or milk products. The processed milk shall be disposed of under the supervision of the regulatory agency.

BULK MILK PICKUP TANKER AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS SCREENING TEST

1. Performance Tests/Controls - Each lot of test kits purchased shall be tested by positive (+) and negative (-) controls in each screening facility prior to its initial use and each testing day thereafter. Records of all positive (+) and negative (-) control performance tests shall be maintained.

2. Initial Drug Testing Procedures - The following procedures apply to testing bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues following the provisions of Appendix N. Industry analysts may screen tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and receive or reject milk. Milk plants, receiving stations, transfer stations, and other screening locations may choose to participate in the Industry Supervisor Certification Program.

a. Industry Presumptive Positive Options - There are two (2) industry options for the milk represented by a presumptive positive sample:

(1) The regulatory agency involved (origin and receipt) shall be notified. The appropriate regulatory agency shall take control of the presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the presumptive positive test results shall follow the initial regulatory agency notification. Testing for

confirmation of that presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be in an Official Laboratory, Officially Designated Laboratory, or by a Certified Industry Supervisor at a location acceptable to the Health Officer. Documentation of prior testing shall be provided to the analyst performing the load and/or raw milk supply that has not been transported in bulk milk pickup tankers confirmation. The presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers may be re-sampled, at the direction of the regulatory agency, prior to analysis with the same or equivalent test (M-I-96-10, latest revision), as was used to obtain the presumptive positive result. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the correct reactions, the sample is deemed a Screening Test Positive (Confirmed Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers Confirmation). A written copy of the test results shall be provided to the regulatory agency. The milk which that sample represents is no longer available for sale or processing into human food.

(2) The owner of the presumptive positive milk may reject the load and/or raw milk supply that has not been transported in bulk milk pickup tankers without further testing. At that time, the milk represented by the presumptive positive test is not available for sale or processing into human food. The milk cannot be re-screened. The Health Officer involved (origin and receipt) shall be notified. Under this option, producer trace backs shall be conducted for the reject load.

Note: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers is found to be positive (confirmed) for drug residues, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

3. **Re-Sampling**

a. Presumptive Results Using Approved Test Methods - Occasionally, an error in sampling or a suspicious test result is discovered after a presumptive result is initially obtained using approved test methods. When this happens, the regulatory agency may allow the industry to re-sample the bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers. The reasons that made the re-sampling necessary shall be clearly documented in testing records and reported to the regulatory agency. This written record shall be provided to the regulatory agency and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

b. Screening Test Results Using Approved Test Methods - Re-sampling or additional analysis of screening test results should be discouraged. However, the regulatory agency may direct re-sampling and/ or analysis, when it has determined that procedures for sampling and/or analysis did not adhere to accepted NCIMS practices (SMEDP, FDA/NCIMS 2400 Forms, Appendix N. and the applicable FDA interpretative or informational memoranda). This decision by the regulatory agency shall be based on objective evidence. A regulatory agency allowing re-sampling shall plan a timely follow-up to identify the problem and initiate corrective action to ensure the problem that led to the need for re-sampling is not repeated. If re-sampling and/or analysis are necessary, it shall include a review of the samplers, analysts, and/or laboratories to identify the problem(s) and initiate corrective action to ensure the problem(s) is not repeated. The reasons that made the re-sampling or analysis necessary shall be clearly documented in testing records maintained by the regulatory agency, and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

Producer Trace Back

a. All screening test confirmed positive loads using an approved test method shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/ permit action) shall be performed in an Official Laboratory, Officially Designated Laboratory, or by a CIS. Positive producers shall be handled in accordance with this appendix.

Note: When a farm bulk milk tank(s)/silos, milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers is found to be confirmed positive for drug residues using an approved test method, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

b. All verified screening positive loads using test methods not evaluated by the FDA and accepted by the NCIMS without additional confirmation required shall be broken down (producer trace back) using the same test method. Verification producer trace back tests shall be performed as cited in a prior documented agreement with the regulatory agency (refer to Section VI). Verified screening positive producers shall be handled in accordance with this appendix.

Note: When a farm bulk milk tank(s)/silos, milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

Assuring Representative Samples From Individual - Producer Loads And Multiple-Farm Tank Loads From An Individual Producer Representative samples shall be secured from each farm storage tank(s)/silo(s) of milk prior to loading onto a bulk milk pickup tanker and/or other raw milk supply transportation method at the dairy farm. The representative sample(s) shall travel with the bulk milk pickup tanker and/or other raw milk supply transportation method to a designated location acceptable to the regulatory agency.

Record Requirements - Results of all testing may be recorded in any format acceptable to the Health Officer that includes at least the following information:

1. Identity of the person doing the test.

2. Identity of the bulk milk pickup tanker or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo, or other raw milk storage container(s), etc. used

for the storage of raw milk supplies that have not been transported in bulk milk pickup tankers being tested*.

3. Date/time the test was performed (time, day, month and year).

4. Identity of the test performed/lot #/any and all controls (+/-).

5. Results of the test, if the analysis results are positive the record shall show:

a. The identity of each producer contributing to the positive load.

b. Who at the Health Officer was notified.

c. When did this notification take place.

d. How was this notification accomplished.

6. Follow-up testing if initial test was positive/any and all controls (+/-).

7. Site where test was performed.

8. Prior test documentation shall be provided for a presumptive positive load.

Include the BTU number(s) of the dairy farms present on the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers with the above information.

SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N FOR BULK MILK PICKUP TANKERS AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS

1. Performance Tests/Controls (+/-):

a. Each lot of kits purchased is tested by positive (+) and negative (-) controls.

b. Each screening facility runs a positive (+) and negative (-) control performance test each testing day.

c. All NCIMS approved bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers screening tests include the following format: All presumptive positive test results shall be repeated in duplicate as soon as

possible at the direction of the regulatory agency on the same sample with single positive (+) and negative (-) controls by a certified analyst (Official Laboratory, Officially Designated Laboratory, or Certified Industry Supervisor) using the same or equivalent test (M-I-96-10, latest revision). If the duplicate tests are negative, with appropriate (+/-) control results, the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers is reported as negative. If one (1) or both duplicate test(s) is positive (+), the test result is reported to the regulatory agency in which the testing was conducted, as a screening test positive (confirmed).

d. All test methods used by industry, which have not been evaluated by the FDA and accepted by the NCIMS for bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers include the following format: One (1) of the options provided for in Section VI of this Appendix shall be followed.

e. All positive (+) controls used for drug residue testing kits are labeled to indicate a specific drug and concentration level for that drug.

(1) For tests that have been validated and only detect Penicillin, Ampicillin, Amoxicillin, and Cephapirin, the positive (+) control is Pen G @ 5 ± 0.5 ppb.

(2) For test kits validated for the detection of Cloxacillin, the positive (+) control may be Cloxacillin @ 10 ± 1 ppb.

(3) For test kits validated for one (1) drug residue only, the positive (+) control is ± 10% of the safe level/tolerance of the drug residue detected.

2. Work Area

a. Temperature within specifications of the test kit manufacturer's labeling.

b. Adequate lighting for conducting the test kit procedure.

3. Test Kit Thermometers

a. Thermometer traceable to a NIST Certified Thermometer.

b. Graduation interval not greater than 1°C.

c. Dial thermometers are not used to determine the temperatures of samples, reagents, refrigerators, or incubators in milk laboratories.

4. Refrigeration

a. Test kit reagent storage temperature specified by manufacturer.

5. Balance (Electronic)

a. 0.01 g for preparation of positive (+) controls.

b. Balance with appropriate sensitivity for calibration of pipetting devices within a tolerance of ± 5%. These devices may be calibrated at another location acceptable to the LEO.

6. Screening Test Sampling Requirements

a. Temperature of milk in the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers determined and recorded.

b. Representative bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers sample for drug residue testing collected.

c. Samples tested within seventy-two (72) hours of collection.

7. Screening Test Volumetric Measuring Devices

a. Single use devices provided by kit manufacturers are acceptable for Appendix N screening analysts.

b. NCIMS certified laboratories require calibrated pipetting/dispensing devices. These devices may be calibrated at another location acceptable to the LEO.

c. Measuring devices with tips bearing calibration lines provided by test kit manufacturers are acceptable for Appendix N screening.

IV. **ESTABLISHED TOLERANCES AND/OR SAFE LEVELS OF DRUG RESIDUES**

"Target testing levels" are used by the FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the target testing levels. In short,

the FDA uses the "target testing levels" as prosecutorial guidelines and in full consistency with CNI v. Young. They do not dictate any result; they do not limit the FDA's discretion in any way; and they do not protect milk producers or milk from court enforcement action.

"Target testing levels" are not and cannot be transformed into tolerances that are established for animal drugs under Section 512 (b) of the FFD&CA as amended. "Target testing levels" do not:

1. Bind the courts, the public, including milk producers, or the FDA, including individual FDA employees.

2. Do not have the "force of law" of tolerances, or of binding rules.

Notification, changes, or additions of "target testing levels" shall be transmitted via Memoranda of Information (M-I's).

V. **APPROVED TEST METHODS**

Regulatory agencies and industry shall use test methods from M-a-85, latest revision, for analysis of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for Beta lactams residues, following the testing procedures specified in Section III of this Appendix. AOAC First Action and AOAC Final Action methods are accepted in accordance with Section 6. Enforcement action based on each test method may be delayed until the evaluation is completed and the method is found to be acceptable to the FDA and complies with the provisions of Rule 420-3-16-.07.

One (1) year after two (2) or more drug test methods have been evaluated by the FDA and accepted by the NCIMS for a particular non-Beta lactam drug or drug family, other unevaluated drug test methods for that particular non-Beta lactam drug or drug family are not acceptable for determining a Screening Test Positive (Confirmation) on a milk tank truck load of milk and/or all raw milk supplies that has not been transported in bulk milk pickup tankers. The acceptance of evaluated drug test methods by the FDA and the NCIMS for drugs other than Beta lactams does not mandate any additional screening by industry or regulatory agencies with the evaluated drug test method, unless it is determined by the Commissioner of the FDA that a potential problem exists with other animal drug residues in the milk supply.

New drug test methods which are submitted to NCIMS from the FDA for acceptance shall not detect drug residues at less than 50 percent of the tolerance level or 25 percent of the target

testing level* for individual drugs, with the exception of the following that may be accepted for Appendix N and other drug testing:

1. Penicillin G at 2 ppb.

2. Tetracycline drug kits that detect tetracyclines at levels greater than 150 ppb for Chlortetracycline, 119 ppb for Oxytetracycline, and 67 ppb for Tetracycline.

*Target testing levels are set by the FDA based on available science. They are not determined by the detection limits of commercially available test methods.

VI. **TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS**

Provided, that until at least two (2) test methods are found acceptable by the FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, and M-I-92-11 in raw milk, non-Beta lactam screening test methods, which have not been evaluated and accepted by the FDA and the NCIMS, may be used for the initial screening, provided that the test method manufacturer's data indicates that testing sensitivity is at or below U.S. target testing/ or tolerance levels.

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR INITIAL SCREENING FOLLOWED BY A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) FOR DETERMINING A SCREENING TEST POSITIVE (LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS CONFIRMATION)

Test methods not evaluated by the FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/ or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues with the documented permission of the regulatory agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the regulatory agency(ies) to determine the facility and protocols to be used to confirm the presence of a non- Beta lactam drug residue with a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11. An M-I-96-10, latest revision, test method(s) shall be used for confirmation.

One (1) of the following two (2) options (1 or 2) shall be used for confirmation:

1. If the initial test result from a drug test method that has not been evaluated by the FDA and accepted by the NCIMS is found to be positive, testing shall promptly be repeated in duplicate with positive (+) and negative (-) controls that give the proper results using the same test method on the same sample. The initial test result is verified as a screening positive when one (1) or both of these duplicate retests give a positive result. The regulatory agency involved (origin and receipt) shall be notified. The appropriate regulatory agency shall take control of the verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the verified screening positive test results shall follow the initial regulatory agency notification. Testing for confirmation of that verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall utilize a test method from M-a-85, latest revision, and M-I-92-11, and shall be conducted in an Official Laboratory, Officially Designated Laboratory, or by a CIS at a location acceptable to the regulatory agency. Documentation of all prior testing shall be provided to the analyst performing the load and/or raw milk supply that has not been transported in bulk milk pickup tanker's confirmation. The verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers may be re-sampled, at the direction of the regulatory agency, prior to analysis with an M-I-96-10, latest revision, test method. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the proper results, the sample is deemed a Screening Test Positive (load and/or raw milk supply that has not been transported in bulk milk pickup tanker's confirmation). A written copy of the test results shall be provided to the regulatory agency. The milk which that sample represents is no longer available for sale or processing into human food. Producer trace back, reporting, and enforcement as defined in this appendix shall occur.

2. If the initial test result from a drug test method that has not been evaluated by the FDA and accepted by the NCIMS is found to be positive, the sample shall promptly be retested using a test method from M-a-85, latest revision, and M-I-92-11. The initial positive M-a-85 and M-I-92-11 test is found to be a presumptive positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The regulatory agency involved (origin

and receipt) shall be notified. The appropriate regulatory agency shall take control of the presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the presumptive positive test results shall follow the initial regulatory agency notification. Testing for confirmation of that presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be conducted in an Official Laboratory, Officially Designated Laboratory or by a CIS at a location acceptable to the regulatory agency. Documentation of all prior testing shall be provided to the analyst performing the load and/or raw milk supply that has not been transported in bulk milk pickup tanker's confirmation. The presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers may be re-sampled, at the direction of the regulatory agency, prior to analysis with an M-I-96-10, latest revision, test method. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the proper results, the sample is deemed a Screening Test Positive (load and/or raw milk supply that has not been transported in bulk milk pickup tanker's confirmation). A written copy of the test results shall be provided to the regulatory agency. The milk which that sample represents is no longer available for sale or processing into human food. Producer trace back, reporting, and enforcement as defined in this appendix shall occur.

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE

Test methods not evaluated by the FDA and accepted by the NCIMS may be used for screening and verifying bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues with the documented permission of the regulatory agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the regulatory agency(ies) to determine the facility and protocols to be used to verify the presence of a non-Beta lactam drug residue.

If the initial test result from a drug test method that has not been evaluated by the FDA and accepted by the NCIMS is found to be positive, the sample shall promptly be retested in a facility identified in the prior documented agreement using the same drug test method. The initial positive test is found to be a verified screening positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The regulatory agency involved (origin and receipt) shall be notified. The appropriate regulatory agency may take control of the verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the verified screening positive test results shall follow the initial regulatory agency notification. The verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be disposed of to remove it from the human or animal food chain. Producer trace back shall be conducted by industry using the same drug test method at the direction of the regulatory agency as cited in the prior documented agreement. If the initial producer test result from the drug test method is found to be positive, the sample shall promptly be retested in a facility identified in the prior documented agreement using the same drug test method. The initial positive test is found to be a verified producer screening positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The regulatory agency shall be notified of the producer trace-back results. The verified screening positive milk is removed from the human and/or animal food chain, which is managed between the user of the test method, the milk supplier, and the dairy producer. Future pickups and/or use of the violative individual producer's milk are prohibited until subsequent testing, utilizing the same drug test method or equivalent that has not been evaluated by the FDA and accepted by the NCIMS, of a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue. Whenever a drug residue test is verified screening positive, an investigation may be completed by the regulatory agency or its agent to determine the cause of the drug residue and actions taken to prevent future violations.

Note: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers is found to be confirmed positive for drug residues using an approved test method or verified screening positive for drug residues using test methods not evaluated by FDA and

accepted by the NCIMS without additional confirmation required, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

Author: G. M. Gallaspy, Jr.
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