

APPENDIX N. DRUG RESIDUE TESTING 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 Section 6 of this *Ordinance*. 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 FDA. (Refer to Section 6 of this *Ordinance*.)

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 shall be retained as determined necessary by the Regulatory Agency.

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/sampler permitted by the Regulatory Agency 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 Regulatory Agency 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 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, farm raw milk tanks/silos (only milk offered for sale) or finished milk or milk product 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 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. THE EXAMINATION OF MILK AND MILK PRODUCTS and at the frequency addressed in Section 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS of this *Ordinance*.

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, 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 positive for drug residues, shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the Regulatory Agency.

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.

Further pickups or 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 Regulatory Agency 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, and
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 results shall be maintained for a minimum of six (6) months by the industry at the location where the tests were run, and/or another location as directed by the Regulatory Agency.

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 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 ten percent (10%) 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 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 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 test the samples. Receiving locations that choose to certify all receiving analysts, 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 Industry Analysts and Industry Supervisors 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. INDUSTRY RESPONSIBILITIES of this Appendix 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 should be an agreement between the Regulatory Agency 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 an agreement between the Regulatory Agency and the industry, or physically supervised by the Regulatory Agency. The milk should be disposed of in accordance with provisions of M-I-06-5 or an FDA and Regulatory Agency reviewed and accepted Beta lactam milk diversion protocol for use as animal feed.
- c. 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. Positive producers shall be handled in accordance with this Appendix.
- d. 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.
- e. 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 Regulatory Agency. At the discretion of the Regulatory Agency, records should be maintained by industry and/or the Regulatory Agency that:
 - (1) Establish the identity of the producer for raw milk supplies that have not been transported in bulk milk pickup tankers that tested positive or the producer and the identity of the load that tested positive; and
 - (2) Establish that ~~no~~ milk is not picked up or used from the drug residue positive producer until the Regulatory Agency has fulfilled their obligations under Section II. ENFORCEMENT of this Appendix 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 Regulatory Agency shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section 6 of this *Ordinance*.

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 Regulatory Agency shall determine the producer(s) responsible for the violation.

Suspension: Any time milk is found to test as a confirmed positive for a drug residue, 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.

Penalties: Future pickups and/or use of the violative individual producer's milk are prohibited until subsequent testing reveals the milk is free of drug residue. 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 positive, 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 Regulatory Agency.
2. Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C. of this *Ordinance*.

Permit Revocation: After a third violation in a twelve (12) month period, the Regulatory Agency shall initiate administrative procedures pursuant to the revocation of the producer's Grade "A" permit under the authority of Section 3. Permits of this *Ordinance*, due to repeated violations.

REGULATORY AGENCY RECORDS:

In regards to the industry reporting a positive 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 Regulatory Agency's directions?
2. When was the Regulatory Agency 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) approved test, which has been promptly repeated 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.
2. **Screening Test Positive (Load or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers Confirmation):** A screening test positive result is obtained when the presumptive positive sample is tested in duplicate, using the same or equivalent (M-I-96-10, latest revision) test as that used for the presumptive positive, with a positive and negative control that give 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 Certified Industry Supervisor using the same or an equivalent test (M-I-96-10, latest revision).
3. **Producer Trace Back/Permit Action:** A producer trace back/permit action test is performed after a screening test positive load is identified by an Official Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an equivalent (M-I-96-10, latest revision) test as was used to obtain the screening test positive (load confirmation). A confirmed producer test positive result is obtained in the same manner as a confirmation (screening test positive) for a load. After an initial positive result (producer presumptive positive) is obtained on a producer sample, that sample is then tested in duplicate using the same test as was used to obtain the producer presumptive positive result. This testing is performed with a positive and negative control and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is confirmed as positive.

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.

4. **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.
5. **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 the 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.

6. **Industry Analyst:** A person under the supervision of a Certified Industry Supervisor or Industry Supervisor 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. drug residue requirements.

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

8. **Certified Industry Supervisor:** An Industry Supervisor who is evaluated and listed by a LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for *Grade "A" PMO*, Appendix N. regulatory 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).

CERTIFIED INDUSTRY SUPERVISORS; EVALUATION AND RECORDS:

Reference: *EML*

1. **Certified Industry Supervisors/Industry Supervisors/Industry Analysts:** Regulatory Agencies may choose to allow Industry Supervisors to be certified. Under this program, these Certified Industry Supervisors 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). In the implementation of Appendix N. of this *Ordinance*, the LEO shall use the appropriate Appendix N. FDA/NCIMS 2400 Form when evaluating Official Laboratories, Officially Designated Laboratories or Certified Industry Supervisors, Industry Supervisors and Industry Analysts.

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, the Regulatory Agency shall be immediately notified. If the bulk milk tanker sample is confirmed positive, 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, 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, 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, as defined in the 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 RAW BULK MILK PICKUP TANKERS of this Section, 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 Regulatory Agency. 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). 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 Regulatory Agency 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:** Occasionally, an error in sampling or a suspicious test result is discovered after a presumptive result is initially obtained. 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:** 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 is 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.

4. **Producer Trace Back:** 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 in an Official Laboratory, Officially Designated Laboratory or by a Certified Industry Supervisor. 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 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.

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 Regulatory Agency 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 Regulatory Agency was notified;
 - c. When did this notification take place; and
 - 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; and
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 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 $\pm 10\%$ 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 $\pm 5\%$. 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

"Safe levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level. In short, FDA uses the "safe levels" as prosecutorial guidelines and in full consistency with *CNI v. Young* stating, in direct and unequivocal language, that the "safe levels" are not binding. They do not dictate any result; they do not limit FDA's discretion in any way; and they do not protect milk producers, or milk from court enforcement action.

"Safe 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. "Safe levels" do not:

- 1. Bind the courts, the public, including milk producers, or FDA, including individual FDA employees; and
- 2. Do not have the "force of law" of tolerances, or of binding rules.

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

V. APPROVED METHODS

Regulatory Agencies and industry shall use tests from the most recent revision of M-a-85 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 lactam 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 of this *Ordinance*. Drug residue detection methods shall be evaluated at the safe level or tolerance. Regulatory action based on each test kit method may be delayed until the evaluation is completed and the method is found to be acceptable to FDA and complies with the provisions of Section 6 of this *Ordinance*.

One (1) year after test(s) have been evaluated by FDA and accepted by the NCIMS for a particular drug or drug family, other unevaluated tests are not acceptable for screening milk. The acceptance of evaluated tests does not mandate any additional screening by industry with the evaluated method.