THE DAIRY PRACTICES COUNCIL®

GUIDELINES FOR CONTROL OF ANTIBACTERIAL DRUGS AND GROWTH INHIBITORS IN MILK AND MILK PRODUCTS

Publication: DPC 22

JANUARY 2004

First Printing – August 1976
First Revision – October 1981
Second Revision – January 1985
Third Revision – January 1990
Fourth Revision – January 1994
Fifth Revision – January 2004

Prepared by:
LABORATORY & QUALITY CONTROL PROCEDURES TASK FORCE
Patrick Boyle, Director
Don L. Breiner, Committee Chair

***Revision Contributors*:**
M. Jeffery Bloom, Larry Maturin, Byron Moyer, Tim Roddy, Robert Salter, Mike Talley and Jim Yeaman

This Revision Sponsored by:
THE DAIRY PRACTICES COUNCIL®
Jeffery M. Bloom, President
Don M. Breiner, Vice President
Terry B. Musson, Executive Vice President

EXCEPTIONS FOR INDIVIDUAL STATES NOTED IN TEXT OR FOOTNOTES
Additional Guidelines may be ordered from:
https://www.dairypc.org
https://www.dairypc.org/catalog/guidelines

ABSTRACT

This guideline is designed to give some general information about the control of antibacterial drugs and growth inhibitors in milk and milk products. It provides recommendations for proper storage of these drugs and for their prevention and detection in milk. It provides a list of test kits that are available for the detection of drug residues in milk, urine, serum and feed. It gives possible causes of antibiotic adulteration and examples of existing penalties and incentives for keeping antibacterial drug residues out of milk and dairy products.

PREFACE

This guideline was originally prepared in August of 1976 by Subcommittee Chairman P. R. Schoech with the assistance of S. E. Barnard, W. B. Hastings, G. F. McPhee, R. N. Mullen and E. R. Thompson, Jr. It was revised October 1981 by co-chairpersons C. W. Hinz and O. C. Bacon with the assistance of S. E. Barnard, D. M. Breiner, P. R. Danilowicz, H. S. Rudnick, H. L. Wildasin and A. F. Zimmermann. C. W. Hinz, Upstate Milk Coop. assumed the responsibility for the 1985 revision with assistance of O. C. Bacon, S. E. Barnard, The Pennsylvania State University, F. D. Barnes-Pallesen, M. A. Brunner, D.V.M., H. L. Wildasin, Ph.D., Consultant, and A. F. Zimmermann, QC, Inc. The 1990 revision was prepared by A. F. Zimmermann, QC, Inc., and D. M. Breiner, Atlantic Dairy Coop. subcommittee chairpersons, assisted by S. E. Barnard, The Pennsylvania State University, C. J. Curtis, Dairylea Cooperative, Inc., M. Clark, New Brunswick Dept. of Agriculture, C. W. Hinz, Upstate Milk Coop., L. J. Hutchinson, DVM, The Pennsylvania State University, B. D. Moyer, Vermont Dept. of Agriculture, H. S. Rudnick, NY State Dept. of Agriculture & Markets, S. T. Sims, FDA, Washington, D.C., and Dr. H. L. Wildasin, Consultant. The 1994 revision was under the leadership of L. S. Hinckley, Department of Pathobiology at the University of Connecticut, assisted by M. J. Bloom, Environmental Systems Service, Ltd., C. W. Hinz, Upstate Milk Coop., B. D. Moyer, Vermont Dept. of Agriculture, Food & Markets, and S. T. Sims, Food & Drug Administration. This 2003 revision is under the committee chairmanship of Donald M. Breiner, Land O' Lakes with committee members: M. Jeffery Bloom, JohnsonDiversey, Inc.; Larry Maturin, Food and Drug Administration; Byron Moyer, Vermont Department of Agriculture; Tim Roddy, Food and Drug Administration; Robert Salter, Charm Science, Inc.; Mike Talley, Food and Drug Administration and Jim Yeaman, IDEXX Laboratories, Inc. providing input.

GUIDELINE PREPARATION AND REVIEW PROCESS

The Dairy Practices Council (DPC) Guideline development and update process is unique and requires several levels of peer review. The first step starts with a *Task Force* subcommittee made up of individuals from industry, regulatory and educational institutions interested in and knowledgeable about the subject to be addressed. Drafts, called "*white copies*," are circulated until all members of the subcommittee are satisfied with the content. The final "*white copy*" may be further distributed to the entire Task Force; DPC Executive Board; state and federal regulators; educational and industry members; and anyone else the Task Force Director and/or the DPC Executive Vice President feel would add strength to the review. Following final "*white copy*" review and corrections, the next step requires a "*yellow cover*" draft to be circulated to representatives of participating Regulatory Agencies referred to as "*Key Sanitarians*." Key Sanitarians may suggest changes and insert footnotes if their state standards and regulations differ from the text. After final review and editing, the Guideline is distributed in the distinctive DPC "*green cover*" to DPC members and made available for purchase to others. These guidelines represent our state of the knowledge at the time they are written. Currently, DPC Guidelines are primarily distributed electronically in pdf format without colored covers, but the process and designation of the steps remains the same. Contributors listed affiliations are at the time of their contribution.

DISCLAIMER

The DPC is not responsible for the use or application of the information provided in this Guideline. It is the responsibility of the user to ensure that the information addresses their needs and that any action taken complies with appropriate regulations and standards.

TABLE OF CONTENTS

INTRODUCTION

Antibacterial drugs and growth inhibitors in milk represent a substantive concern which the dairy industry clearly recognizes, and has taken prompt, effective, and responsible actions to correct. This guideline provides an update (as of January 1, 2004) on the methods and procedures to use in controlling and limiting antibacterial drug residues and growth inhibitors in the milk supply.

Drug residues occur on the farm, not later in the processing channels. Labeling and storage requirements at the farm level exist as part of the total endeavor by federal and state regulatory agencies, the National Conference on Interstate Milk Shipments (NCIMS), dairy processors, dairy producers, and the veterinary medical profession to avoid drug residues.

Due to the heightened concern related to drug residues and the current requirements of the Grade "A" Pasteurized Milk Ordinance (PMO) Appendix N, all milk regulatory agencies and industry have increased monitoring for antibacterial drug residues in milk. Universal sampling has increased the rate of drug residue detection. Improvements in testing methods allowing a lower limit of detection have revealed violations where none were thought to exist.

The elimination of antibacterial drug residues and growth inhibitors in milk and dairy products is a total industry concern that demands the involvement of all responsible people in the dairy industry and government. Total participation in the education, control and enforcement aspects of an effective antibacterial drug residue control program is a must. Both farmers and processors want a favorable reception in the marketplace. Antibacterial drug residues are illegal and cannot be tolerated. Preventing contamination is the only answer, since processing cannot eliminate antibacterial drug residues. Most dairymen will respond, if they are aware of the problem and are informed of the proper procedures to follow.

A single contaminated lot of milk can adulterate tens of thousands of pounds of storage tank milk. An infusion of 1,000,000 units of penicillin G would be measurable in 450,000 pounds of milk. Producers must follow instructions pertaining to the use of all antibacterial drugs, and they must have positive control to prevent contamination of milk. The source of antibacterial drug residues, such as penicillin, is from treated dairy cows and must be controlled at the farm. Receivers of milk need to use the most sensitive, well-validated testing procedures available. The development of testing equipment now permits detecting growth inhibitors and some individual antibacterial drug residues at a very low level. Milk samplers should carry dippers in chlorine or iodine sanitizers of the proper strength. Rinse dippers at least twice in the milk supply before collecting samples. Dairy farmers must be certain no sanitizing solution adulterates milk offered for sale.

RECOMMENDATIONS FOR PREVENTION

Drugs are not an acceptable substitute for good management. Disease prevention (particularly for mastitis) is based on good sanitation and use of a complete herd health program, i.e., vaccinating for common diseases and segregating cows that are infected carriers. Good management practices both prevent the stress that can lead to infections and disease spread among animals and reduce the need for antibacterial drugs.

Use only approved and properly labeled animal drugs.

Know the kind of drug being used and what effects are expected. Don't use questionable preparations. The experienced suppliers have spent large sums of money in attempting to assure that their label declarations are correct, and the Food and Drug Administration (FDA) must approve the label wording. All antibacterial drugs such as penicillin, tetracycline, streptomycin, sulfamethazine and other combinations of

these drugs MUST be kept out of the market milk. This also includes eyedrops, ointments and other preparations containing drugs or combinations of drugs. Some teat dilators and uterine boluses can also cause drug residues in milk.

Read the label for dosage requirements. Follow label directions explicitly. DO NOT EXCEED PRESCRIBED DOSAGE. If, for example, two tubes instead of one are used, the drug may not clear the cow in the usual length of time. Dose rate and excretion rate of some drugs are related. Sometimes even at normal treatment rates a drug can stay with a cow longer than label warnings indicate due to the level of milk production or age of the cow, or state of health of the animal at the time of treatment.
Read the label to determine the length of time milk must be withheld from sale. DO NOT CUT THIS TIME SHORT OR DEPEND ON A DILUTION EFFECT. All labels should specify the amount of antibiotic to administer, route of administration and the appropriate withholding time for the milk. The withholding time is usually 72-96 hours. If a drug will not clear in 96 hours, it is not normally used on lactating cows. Good insurance is to have the milk from each treated cow tested and found negative before putting this milk into the bulk tank. This service is usually available from an industry field representative or veterinarian.

Extra-label[1] use means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.

Only licensed veterinarians can prescribe the extra-label use of a drug.

The FDA allows extra-label drug use only if the following criteria are met:[2]

(a) The following conditions must be met for a permitted extra-label use in food-producing animals of approved new animal and human drugs:

(1) There is no approved new animal drug that is labeled for such use and that contains the same active ingredient which is in the required dosage form and concentration, except where a veterinarian finds, within the context of a valid veterinarian-client-patient relationship, that the approved new animal drug is clinically ineffective for its intended use.

(2) Prior to prescribing or dispensing an approved new animal or human drug for an extra-label use in food animals, the veterinarian must:

(i) Make a careful diagnosis and evaluation of the conditions for which the drug is to be used;-

(ii) Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information, if applicable;

(iii) Institute procedures to assure that the identity of the treated animal or animals is carefully maintained; and

(iv) Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extra-label treatment.

[1]Extracted from; 21 CFR 530.20
[2]Extracted from; 21 CFR 530.3

(b) The following additional conditions must be met for a permitted extra-label use in food-producing animals of an approved human drug, or of an animal drug approved only for use in animals not intended for human consumption:

(1) Such use must be accomplished in accordance with an appropriate medical rationale; and

(2) If scientific information on the human food safety aspect of the use of the drug in food-producing animals is not available, the veterinarian must take appropriate measures to assure that the animal and its food products will not enter the human food supply.

(c) Extra-label use of an approved human drug in a food-producing animal is not permitted under this part if an animal drug approved for use in food-producing animals can be used in an extra-label manner for the particular use.

Certain drugs (such as chloramphenicol, diethylstilbestrol, and dimetridazole) cannot be safely used in treating food-producing animals even under the cited criteria.

Veterinarian-Client-Patient Relationship[1]

(i) A valid veterinarian-client-patient relationship is one in which:

(1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;

(2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

(3) The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

However, even following these criteria, however, FDA will consider regulatory action nonetheless if illegal drug residues are found in treated animals. Therefore with extra-label use be very sure to follow the veterinarian's recommended withholding time.

Keep detailed permanent records of all cows treated. Include cow number, person, time, date, drug, dosage of drug administered and other information such as route (i.e., intravenous, intramuscular or intramammary), breeding, freshening, proper drying off, and dry cow therapy.

Identify all cows treated so that all persons having anything to do with the milking operation know which cows should not be milked in the routine manner. A means of identifying treated animals is to mark both flanks or milking side with day of week and morning or afternoon milking when milk is safe to add to supply (i.e., **Wed./am.** or **Sun./pm)** Marking crayons, magic markers in vivid colors, and ankle bands are available for this purpose. Lack of communication is perhaps the most common cause of antibacterial drug residue contaminated milk. According to one study, 40% of accidental adulteration occurs in this manner.

Segregate treated cows from the herd and milk treated cows last. One should make certain that all milk contact surfaces are thoroughly cleaned and sanitized after milking treated cows. This avoids problems of carry-over of treated milk on the equipment to untreated milk. A single medicine dropper of milk from a treated cow can cause detectable levels in the next cow's milk passing through the same equipment. In milking parlors and pipeline milking systems, separate bucket type milkers should be provided so that milk from treated cows can be kept out of the milk supply line to the bulk tank. (Vacuum provided to these buckets cannot be from the milk line connected to the bulk tank or from a vacuum line connected to the

milk line) Hospital quarters should be provided to permit complete segregation of treated animals from the milk herd.

Discard all milk from treated cows, even if only one quarter has been treated. Milk from the other three-quarters may also be contaminated.

If calves receive milk containing antibacterial drug residues from treated cows, they should not be slaughtered until the slaughter withholding times for the specific antibiotic residues in the milk have been met.

One person should be responsible for administering all drugs and identifying all animals treated. This should reduce accidental contamination due to poor communication. If the veterinarian treats a cow in the absence of the herdsman, they should provide adequate written information for the herdsman before leaving the farm.

Dry cows should not be treated with dry-cow mastitis tubes within four weeks (28 days) of freshening, and milk should not be added to the supply for at least 96 hours after freshening. Milk may be contaminated from cows calving prematurely after dry cow treatment. Dry cow treatment antibiotic formulations are long lasting and generally require a 30-day withholding period. This 30-day withholding period extends through freshening for the full period. Even when cows freshen on time, a milk-withholding period is often required. Read the label! **Dry cow treatment should never be used on lactating cows**. If treated by accident, milk should be withheld until tested and found negative by a laboratory.

Antibacterial drug injections by any route of administration: intravenouses, intramuscular, intramammary or subcutaneous are absorbed into the bloodstream and eventually **contaminate the milk**. Withhold this milk from market for the prescribed period of time. Withholding times for intramuscular and intrauterine antibacterial drugs are generally longer than for intramammary infusions. Uterine infusion is a good example of a treatment that is likely to lead to detectable antibiotic residue in milk. When used to treat the uterus of cows suffering from metritis (inflamed uterus) or retained placenta, tetracyclines that formerly went undetected in milk can now result in positive tests. For example, the new test procedure can now detect residues in milk caused by a 2.5 g dose of tetracycline in a normal uterus for 12 hours in most cows and 24 hours in some cows. A dose of 10 grams of tetracycline (a fourfold increase in the routine dosage) in a normal uterus can result in detectable residue levels in milk for up to 48 hours.

Milk from lactating cows just purchased or under treatment should be checked before adding the milk to the supply. Handle new cows in the herd as though they had just been treated. Withholding the milk from the bulk tank for at least 5 days or until tested negative. **This is probably the second most common source of antibiotic residue contamination**.

Observe specific withholding times for all medications and remember that oral, topical, and intramuscular medications can all be secreted in the milk. Therefore, regardless of the routes of administration, or the type of medication, do not put milk from treated cows into the bulk tank until the withholding time for the medication has expired.

Do not use hog or poultry feed for cows. Do not let cows get into any feed intended for other livestock. Do not prepare feed for cows in a mixer that was previously used for preparing hog or poultry feed. Levels of antibacterial drugs in hog and poultry feed may be significantly higher than those allowed for cows. Check with feed supplier to insure that cross contamination in mixing operation does not occur. Always clean out mixing bins carefully before preparing a feed for dairy cows. If feed containing antibacterial drugs is used, do not overfeed. Follow label directions. The amount of antibiotic in feed is controlled by government regulation.

Treated cows should be milked completely. The more completely a cow is milked out, the faster any drug will clear out.

When treated cows are shipped to slaughter, remember that the withdrawal time following treatment is much longer for tissue residues than is the **withholding time** for milk. **It may be up to 60 days**. Check the label, and do not ship them until the recommended time has elapsed.

TEST THE MILK FROM EVERY TREATED ANIMAL PRIOR TO ADDING THE MILK TO YOUR BULK TANK. When testing milk from treated cows, use a residue screening test that is accurate for the type of drug (or active ingredient stated on the label), which was administered.

TEST A SAMPLE WHENEVER IT IS SUSPECTED THAT MILK CONTAINING ANTIBIOTIC RESIDUES WAS PUT INTO THE BULK TANK. Dairy farmers must dump a bulk tank of milk if results of official tests are positive. Industry sanitarians may recommend dumping milk based on positive screening test results. However, regulatory sanitarians should only rely on official laboratory test results when requiring milk to be dumped. A guideline for the avoidance of drug residues is printed in the Quality Assurance Program Manual entitled Milk and Dairy Beef Residue Prevention Protocol which is available from:

Milk and Dairy Beef Quality Assurance Center
801 Shakespeare, Box 497
Stratford, IA 50249
(515) 838-2793, FAX (515) 838-2788

DRUG STORAGE

The Food & Drug Administration through the National Conference on Interstate Milk Shipments (NCIMS) has established regulations which mandate the proper use and storage of animal drugs on dairy farms. These regulations require that only drugs that are approved and properly labeled for dairy cattle can be administered to dairy cattle. Non-dairy cattle drugs **must not** be used on dairy cattle and **must not** be stored in the dairy production area. Only those drugs approved and properly labeled, including extra label drugs, for dairy cattle shall be stored in the milkhouse, milking barn, stable or parlor, or adjacent areas.

Item 15r in PMO Grade "A" PMO cites Specific Drug Labeling and Storage Requirements.

Antibacterial drugs and medicinals are stored in such a manner that they cannot contaminate the milk or milk product contact surface of the equipment, containers or utensils. Such products shall be properly labeled to include:

1. The name and address of the manufacturer or distributor (for over-the-counter medicinals/drugs), or veterinary practitioner dispensing the product (for prescription and extra-label use medicinals/drugs);

2. The active ingredient of the medicinal/drug;

3. Directions for use, and prescribed withholding times; and

4. Cautionary statements, if needed.

Unapproved and/or improperly labeled medicinals/drugs are not used to treat dairy animals and are not stored in the milkhouse, milking barn, stable or parlor. Medicinals/drugs intended for treatment of non-lactating dairy animals are segregated from those medicinals/drugs used for lactating animals. (Separate shelves in cabinets, refrigerators or other storage facilities satisfy this item.)

NOTE: Topical antiseptics, wound dressing, (unless intended for direct injection in the teat) vaccines and other biologics, and dosage form vitamins and/or mineral products are exempt from labeling and storage requirements except when it is determined that they are stored in such a manner that they may contaminate the milk or milk product surfaces of containers or utensils.

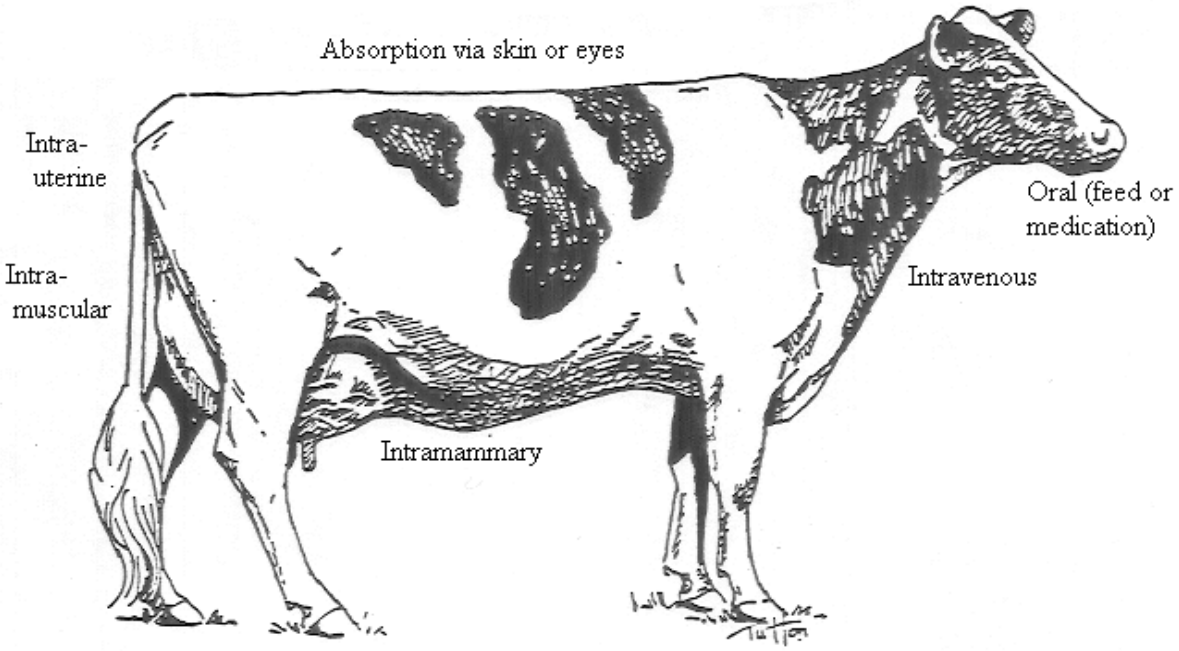
Improper use and storage of animal drugs on dairy farms can cause a debit on your routine regulatory inspection and during your IMS dairy farm rating or FDA check rating.

RECOMMENDATIONS FOR DETECTION

A representative universal sample should be taken from each bulk tank at every pickup.

- A composite tanker sample of all producers' milk properly agitated should be taken from the bulk tank truck before unloading. This sample should be immediately analyzed for Beta-lactams or other inhibitor by an acceptable method.
- If the composite tanker sample is positive, each representative universal sample should be analyzed to determine which producer caused the adulteration. The official test performed on the producer sample must be performed in an officially designated laboratory using a test procedure (see test procedures, page 15) acceptable to both FDA and the state regulatory agency when official action is anticipated. The producer should be immediately notified of a positive test result.
- All positive samples should be held in frozen storage until all chances of legal action are exhausted Frozen samples are not acceptable for use in the NCIMS Program.
- EACH HANDLER SHOULD HAVE ON RECORD THE ANTIBIOTIC TESTS RESULTS FOR EACH LOAD OF MILK PURCHASED, TRANSFERRED, OR SOLD.

POSSIBLE CAUSES OF ANTIBACTERIAL DRUG, ADULTERATED MILK



Eye drops for pinkeye treatment
Antibiotic wound ointments
Some teat dilators
Uterine boluses

Vaccines and semen containing antibacterial drugs as preservatives are not significant sources of antibacterial drug residues in milk.

This appendix is established to reference safe levels and/or established tolerances and to assure that milk supplies comply with these safe levels or established tolerances for drug residues in milk.

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE (2003 PMO)

I. INDUSTRY RESPONSIBILITIES

A. Monitoring and Surveillance

Industry shall screen all 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. The random bulk milk pickup tanker 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 the PMO)

The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. The sample must be representative. Bulk milk pickup tanker testing shall be completed prior to processing the milk. 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*. Bulk milk pickup tanker samples found to be positive for drug residues shall be retained as determined necessary by the Regulatory Agency. All presumptive positive test results for drug residues from analysis done on commingled raw milk tanks, bulk milk pickup tankers, farm raw milk tanks (only milk offered for sale) or finished milk or milk product samples must be reported to the Regulatory Agency.

B. Reporting and Farm Traceback

When a bulk milk pickup tanker is found to be positive for drug residues, the Regulatory Agency 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.

Further pickups of the violative individual producer's milk shall be immediately discontinued, until such time, that subsequent tests are no longer positive for drug residues.

C. 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 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 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 farms present on the bulk milk pickup tanker 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

A. 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 to review industry re- cords of the sampling program. Samples should be collected and analyzed from at least 10% of the 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.

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 I. A. 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 milk, and of the trace-back to the farm of origin?

5. Is the farm pickup 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 would specify how this notification is to take place. This notification must be "timely" for example by telephone or fax, and supported in writing.

b This 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 the provisions of M-I-90-9 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 must 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 or Officially Designated Laboratory or Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.

d The suspension and discontinuance of farm bulk milk tank pick up 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 and the identity of the load that tested positive; and

(2) Establish that no milk is picked up from the positive testing producer until the Regulatory Agency has fulfilled their obligations under Part II., B. of this Appendix and cleared the milk.

Sufficient records should be reviewed to assure that all farm bulk milk pickup tankers are sampled before commingling 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 the PMO.

B. 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 pick-ups 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 plus any costs associated with the disposition of the contaminated load. 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.

C. Regulatory Agency Records

In regards to the industry reporting a positive tanker result, the Regulatory Agency's records should 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?

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

A. 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 tanker using an M-a-85 (latest revision) approved test which has been promptly repeated in duplicate with positive and negative controls using the same test, on the same sample, with one or both of these duplicate retests giving a positive result.

2. Screening Test Positive (Load 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, and either or both of the duplicates are positive and the controls give the proper results. A screening test positive (load confirmation) is to be preformed by an Official State 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 State 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.

4. Individual Producer Load: An individual producer bulk milk pickup tanker is a tanker, or a compartment of a tanker, that contains milk from only one (1) dairy farm.

5. Industry Analyst: A person under the supervision of the Certified Industry Supervisor or Industry Supervisor who is assigned to conduct screening of bulk milk pickup tankers for Appendix N. drug residue requirements.

6. Industry Supervisor/Certified Industry Supervisor: An individual trained by the State LEO who is responsible for the supervision and training of Industry Analysts who test bulk milk pickup tankers for Appendix N. drug residue requirements.

7. Certified Industry Supervisor: An Industry Supervisor who is evaluated and listed by a State LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for PMO, Appendix N. regulatory actions (confirmation of tankers, producer trace back and/or permit actions).

B. Certified Industry Supervisors; Evaluation and Records
References: EML and IMS-a-30, Supplement 2

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 tanker loads and confirm producer milk for regulatory purposes (producer trace back/permit action). In the implementation of Appendix N. of this *Ordinance*, the LEO will use the appropriate Appendix N. 2400 Series Form when evaluating Official State 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 result 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 State LEO and updated as replacement, additions and/or removals occur. The State 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 State 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 State LEO and the LQAT 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 IMS-a-30, Supplement 2, 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 must be representative. The sample analysis shall be completed before the milk is processed.

3. 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 positive, the Regulatory Agency shall be immediately notified. 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.

C. Bulk Milk Pickup Tanker 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 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 for drug residues following the provisions of Appendix N. Industry analysts may screen 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. A written copy of the presumptive positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that presumptive positive load shall be in an Official State 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 confirmation. The presumptive positive load 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). 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 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.

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. 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.

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 (Standard Methods, 2400 Series Forms, Appendix N. and the applicable FDA interpretative or informational memoranda). This decision by the Regulatory Agency must be based on objective evidence. A Regulatory Agency allowing re-sampling must 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.

4. Producer Trace Back:

All screening test positive (confirmed) loads must 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 State Laboratory, or Officially Designated Laboratory or by a Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.

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) of milk prior to loading onto a bulk milk pickup tanker at the dairy farm. The representative sample(s) shall travel with the bulk milk pickup tanker 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 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 should 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 farms present on the bulk milk pickup tanker with the above information.

SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N. FOR 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 Screening Tests Include The Following Format: All presumptive positive test results are to 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 State Laboratory, Officially Designated Laboratory or Certified Industry Supervisor) using the same or equivalent test (M-I-96-10, latest revision). If the duplicate tests, with appropriate control (+/-) results are negative (-), the tanker is reported as negative. If one or both duplicate test(s) is positive (+), the test result is reported to the Regulatory Agency as a screening positive.

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 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 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 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 State LEO.

6. Screening Test Sampling Requirements:
   a. Temperature of milk in the bulk milk pickup tanker determined and recorded.
   b. Representative bulk milk pickup tanker 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 State 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 prosecutional 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 the Agency'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 the Agency, 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" will 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 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 the *PMO*. 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 the PMO.

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.

SOURCES OF ASSISTANCE

A producer who is uncertain about treatment or withdrawal time should reread the label and if further information is needed, he should contact either the vendor of the product, the local veterinarian, the field representative, or the appropriate person in state government or cooperative extension.

One source of information on antibacterial drugs and withdrawal times is contained in a publication entitled "A Comprehensive Compendium of Food Animal Drugs". The cost is $5.00 for Dairy Cattle and $11.00 for the complete volume (all farm animals), plus 6% sales tax for Florida residents.

Check, money order or purchase order (government agencies ONLY) should be sent to:

Publications Institute of Food & Agri. Sciences
Building 664
University of Florida
Gainesville, Florida 32611
Tel. 904-392-4085

The above information from the University of Florida is compiled from FARAD (Food Animal Residue Avoidance Data bank). FARAD maintains current label information including withdrawal and milk discard times on all drugs approved for use in food animals in the US and on hundreds of products approved in Europe. Official tolerance values for drugs and pesticides in tissues, milk and eggs are accessible through FARAD as is physicochemical information on approximately 300 compounds.

The majority of information contained in FARAD pertains to residue depletion times for drugs, pesticides, and other chemicals in food animals. By drawing from this information base, FARAD personnel are able to answer wide range of questions about the depletion of residues in milk and tissues when drugs are given by various routes.

NOTE: Data bank information is not necessarily from scientific studies. It gives useful information about how long drugs may be found in milk but may not give verifiable information about when milk will be clear of these residues.

EFFECT ON CULTURED PRODUCTS

Antibacterial drugs and other growth inhibitors pose a serious problem for the manufacture of cultured products. The organisms used in these products are inhibited by very low levels of most antibacterial drugs. Sanitizing agents, especially quaternary ammonium compounds, may cause serious loss of activity of some culture organisms.

Unfortunately, regulatory agencies appear to have stressed just the health aspects of antibacterial drugs, especially penicillin, and have often ignored the practical effects of reduced culture activity in cultured products. Not only do antibacterial drugs and sanitizers reduce culture activity and cause poor quality or complete loss of cultured products, but the lack of acid development may permit the development of many undesirable organisms. An outstanding example of the latter is the possible growth of toxin-producing staphylococci that may cause food poisoning.

SUMMARY

In summary, it is essential for animal health that antibacterial drugs continue to be available. Misuse of antibacterial drugs jeopardizes this continued availability. Antibacterial drugs are not a substitute for good herd management. The saying, "If all else fails, read the label", should be reversed to "Read the label first--and not just read the label--but HEED the label". If this is done, and treated cows are segregated and tested before returning to the milking herd, we will have gone a long way toward eliminating antibiotic residues in milk and milk products.

Note: Please see page 18 for **Test Procedures Available**. This section will be updated when necessary.

TEST PROCEDURES AVAILABLE *

FDA in conjunction with the AOAC Research Institute and the A. D. Little Co. has conducted an evaluation of milk screening tests for beta lactam drugs. The table below presents the tests and their respective drugs of detection that have been found to be acceptable for use in fulfilling the testing requirements of PMO Appendix N:

MILK DRUG RESIDUE SCREENING TEST DETECTION CONCENTRATIONS[1]
BETA lactams

DRUG	Amoxicillin	Ampicillin	Ceftrofur	Cephapirin	Cloxicillin	Penicillin
Tolerance or Safe Level	10ppb	10ppb	50ppb	20ppb	10ppb	5ppb
Screening Test						
Charm B. stearothermophilius Tablet Disk Assay[12,14]	7.5	6.7	75[7]	11.7	48[7]	3.8
Charm II Tablet Beta lactam Test (Competitive Assay)[12]	7.5	5.7	7.1	4.2	70[7]	3.0
Charm II Tablet Beta lactam Test (Sequential Assay)	8.1	6.6	11.3	4.1	50[7]	3.4
Charm SL Beta lactam Test[11]	5.6	8.5	46.2	13.7	50[7]	3.6
Charm SL6^{TM} Beta lactam Test	7.1	9.6	37.5	18.7	8.3	4.2
Charm II Tablet Beta lactam Test (Quantitative Assay)[3]	8.1	6.6	11.3	4.1	8.5	3.4
Charm II Tablet Transit Beta lactam Test[4]	7.5	5.7	7.1	4.2	50[7]	4.5
Charm II test for Cloxacillin in Milk (Competitive Assay)[5,12]	ND[6]	ND[6]	ND[6]	ND[6]	8.5	ND[6]
Delvotest P 5 Pack[12,13,14]	4.6	4.0	NA[8]	8.2	NA[8]	2.1
Delvotest P/ Delvotest P Mini[14]	7.7	5.1	>50	7.0	30[7]	3.1
Delvotest SP/ Delvotest SP Mini	6.0	7.9	>50	7.7	33[7]	2.7
Delvo-X-PRESS Beta lactam Residue Test Kit	9.2	7.0	11.5	4.1	50[7]	4.7
Penzyme Milk Test[14]	6.0	7.0	80	11.6	80[7]	5.0
Penzyme III Test Procedure[14]	5.3	5.6	NA[8]	14.3	NA[8]	4.3
Snap Beta lactam Residue Test Kit (Reader)[9,12]	8	8.2	10.5	3.5	50[7]	3.5
Snap Beta lactam Residue Test Kit (Visual)[9,12,14]	9.4	8.2	9.6	3	50[7]	3.4

* Approved Test Procedures Taken from FDA Milk Safety Branch Memo M-a-85 (Revision 10) dated May 30, 2003.**Refer to the most recent revision**

New Snap Beta lactam Test Kit[9]	7.3	5.8	5.4	11.7	50[7]	3.0
Parallux Beta lactam Assay	3.6[10]	2.9[10]	33.7	16.3	7.4	3.2[10]

FOOTNOTES:

1. Parts per billion (ppb), which can be detected 90% of the time with 95% confidence. Additional drug level response data are provided for each test in the following tables and should be considered when selecting drug residue monitoring tests. The 90/95% concentrations (ppb) were determined by fitting a statistical model to the dose response data designed to estimate this value. The lower, one-sided 95% confidence limit was used. This data was either collected at an independent laboratory or the test samples were prepared at an independent laboratory.

2. Parent Drug

3. Test sensitivity when presumptive positive milk samples are verified in accordance with label directions using the Charm II Tablet Sequential Assay and the Charm II Test for Cloxacillin in Milk.

4. The Charm II Tablet Transit Test requires the use of a composite sample. Sampling techniques used to obtain these samples should be evaluated and accepted on a State-by-State or case-by-case basis.

5. For Appendix N bulk milk tanker screening, this test must be used in combination with other approved screening methods in order to detect at least four (4) of the six (6) targeted Beta lactam drugs.

6. ND indicates "Not Detected"

7. 90/95% concentrations were not determined for sensitivities significantly above the tolerance/safe level.

8. NA indicates "Data Not Available"

9. The SNAP Beta lactam Test is being replaced by the New SNAP Beta lactam Test. The visual reading option is not available with the New SNAP.

10. For Parallux tests, due to significant cross reactivity of cloxacillin in the Cillins channel, a positive Cillins test may be due to cloxacillin.

11. The Charm SL Beta lactam Test is acceptable for testing raw, commingled goat milk (M-I-03-3).

12. This test is acceptable for use to detect Beta lactam residues when used with pasteurized whole milk and pasteurized skim milk.

13. This test is acceptable to detect ampicillin, amoxicillin, cephapirin and penicillin residues in fat-free chocolate, whole chocolate, half & half, heavy cream and pasteurized goat milk.

14. Refer to M-I-01-4 for certification requirements to use this visual test.