

## **Collection of Milk Samples from Known Tissue Residue Violators Questions and Answers**

1. How is milk currently tested for the presence of drug residues?

FDA and the states currently participate in the National Conference on Interstate Milk Shipments (NCIMS), a voluntary coalition of regulators established to ensure the safety and wholesomeness of fresh milk in the United States. FDA publishes the Grade A Pasteurized Milk Ordinance (PMO) as a model ordinance for states to adopt. The PMO requires bulk milk pick-up tankers be tested for the presence of at least four of the six specific beta-lactam drugs (penicillin, ampicillin, amoxicillin, cloxacillin, cephapirin, and ceftiofur). Each tanker of milk is currently only routinely tested for beta-lactam residues prior to being processed for food.

2. What are beta-lactam drugs?

Beta-lactam antibiotics are a broad class of antibiotics that include penicillin derivatives (penams), cephalosporins (cephems), monobactams, and carbapenems. They are the most widely-used group of antibiotics. However, there are many other classes of drugs potentially used on farms that are not routinely tested for in milk. These include sulfonamide antibiotics such as sulfamethazine, aminoglycoside drugs such as gentamicin, and anti-inflammatory drugs like flunixin.

3. Can you briefly explain FDA's milk sampling assignment?

FDA plans to issue a sampling assignment to determine if farms previously identified with drug residues in meat have inadequate farm management practices such as failure to maintain treatment records or identify treated animals that may also lead to drug residues in milk.

The sampling assignment would target only egregious tissue residue violators, those with the highest risk scores that have been known to ship adulterated food (meat) in interstate commerce.

4. Why is FDA issuing this sampling assignment?

The intent is to conduct the sampling assignment with the cooperation of the states and the milk industry to specifically target those dairies with a history of drug residue violations involving tissues from dairy cows offered for slaughter. The data obtained from this assignment will provide evidence as to whether the practices on these dairies that have resulted in tissue residue violations are also creating potential milk safety concerns.

FDA works with USDA and the states to monitor meat, poultry, and milk for unapproved or unsafe drug residues. The residue program for meat and poultry involves USDA's Food Safety and Inspection Service (FSIS) testing meat and poultry for a variety of drug residues including beta-lactams and many other classes

of drugs and reporting violative findings to FDA for follow-up and potential enforcement action. FSIS commonly finds non-beta-lactam drug residues in meat including sulfonamides, aminoglycosides, and non-steroidal anti-inflammatory drugs.

Although only 7.7% of the cattle slaughtered in the United States are adult dairy cattle, they represent an average of 67% of the tissue residue violations reported by USDA's FSIS during the past 5 years.

A well-managed dairy farm maintains records of each animal treated, what it was treated with, when it was treated, and how it was treated, for example the route of administration, dosage and duration of treatment. Such records are used by producers so that they can ensure that treated cows put back into the milking string or sold for slaughter have met appropriate drug withdrawal times in order to prevent illegal drug residues in meat and milk.

Drug residue violations in dairy cattle tissues often result from poor practices on the farm. These practices may include: failure to maintain treatment records, failure to follow labeled withdrawal times, failure to identify treated cows, increasing the labeled dosage, increasing the length of treatment, or giving the drug by an unapproved route of administration, i.e., intramuscular vs. intravenous.

FDA is concerned that the same poor management practices which led to the meat residues may also result in drug residues in milk, especially from non-beta lactam drugs.

5. How will FDA determine which farms/producers to sample?

The sampling assignment will include dairy violators that have had tissue residues with the highest risk scores.

6. How are risk scores calculated?

The Risk Model takes into account the hazard associated with the drug, the likelihood of exposure, and the exposure level.

7. Who would collect the samples?

The samples may be collected by a trained FDA investigator.

8. How would the samples be collected?

The farm bulk milk tank will be sampled in duplicate collecting two (2) 4-fluid ounce samples at a minimum.

9. How many and which drugs will be tested?

The milk samples will be tested for over 25 different drugs commonly used on dairy farms. They are: Ampicillin, Cephapirin, Cloxacillin, Penicillin G, Erythromycin, Tylosin, Enrofloxacin, Sarafloxacin, Chlortetracycline, Oxytetracycline, Tetracycline, Doxycycline, Sulfachloropyridazine, Sulfadiazine, Sulfamerazine, Sulfadimethoxine, Sulfamethazine, Sulfapyridine, Suflaquinolaxine, Sulfathiazole, Tripelennamine, Thiabendazole, Pirlimycin, Flunixin, Bacitracin, Virginiamycin, and Tilmicosin

10. What method will be used to analyze the milk samples?

A multi-class, multi-residue liquid chromatography/tandem mass spectrometry screening and confirmation method will be used to identify violative drug residues in milk.

11. Why is milk currently only tested for beta lactam antibiotics?

When Appendix N of the Pasteurized Milk Ordinance was implemented under the Federal/State National Conference on Interstate Milk Shipments (NCIMS) the only available quick screening tests in milk were for the beta lactam class of drugs.

12. What happens if the samples are positive for drugs?

When a violative milk sample is reported to an FDA District by an FDA laboratory, an inspection to document the violation will be conducted according to Compliance Program 7371.006. If the analysis of the collected milk sample shows the presence of drug residues above established tolerances and/or the use of any unapproved new animal drug(s) and responsibility for the violation can be documented, CVM will consider taking regulatory action for the drug adulteration. CFSAN will conduct a Health Hazard Assessment of any milk residue(s) to determine the need for possible recall and/or food adulteration charges.

13. Is the milk supply in the U.S. safe?

FDA has not previously held the view, nor does it now hold a view, that the nation's milk supply is unsafe due to animal drug residues. Efforts such as this sampling assignment will ensure that any problem that may exist remains minor and is quickly mitigated by education and enforcement, as appropriate. FDA is targeting the few members (tissue residue violators) of an otherwise compliant industry in order to ensure that the public can have the utmost confidence in the dairy products they consume.