

KEY MESSAGES AND QAs: 2012 Milk Drug Residue Sampling Survey

SECTION I: TOP LINE MESSAGES

1. The results from the FDA's survey of milk from nearly 2,000 dairy farms found that more than 99 percent of the samples are free of drug residues of concern-- underscoring the safety of the U.S. milk supply.
2. These findings provide evidence that the nation's milk safety system is effective in helping to prevent drug residues of concern in milk, even in those limited instances when medications are needed to maintain the health of dairy cattle.
3. Efforts such as this sampling assignment reflect a continuous commitment to maintain the strongest possible system to ensure milk safety.

SECTION II: KEY MESSAGES

1. The results from the FDA's survey of milk from nearly 2,000 dairy farms found that more than 99 percent of the samples are free of drug residues of concern-- underscoring the safety of the U.S. milk supply.
 - The survey was designed to determine whether farms with previous drug residue violations in tissue derived from dairy cows were more likely to have violative drug residues in milk than other dairy farms.
 - For decades, the FDA and state regulatory officials have worked to ensure the highest safety standards for milk. The FDA is continuously looking for ways it can improve its food safety efforts.
 - The FDA found that 15 out of 1,912 milk samples contained drug residues of concern. Eleven of the positive samples came from the targeted group (farms with previous tissue residue violations) and four came from the non-targeted group (control group).
 - The difference in the number of positive samples in the targeted group (i.e., farms with previous tissue residue violations) compared to the number in the control group was not statistically significant.
 - The survey detected the presence of classes of drugs that are not routinely tested for under the current milk safety program, particularly in the targeted group of previous violators. The results will inform FDA as it develops a risk ranking for drug residues in milk and ultimately assists regulators in modifying testing, as necessary, to include testing for more diverse drug classes.
 - The detailed results of the survey are available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM435759.pdf>.
2. These findings provide evidence that the nation's milk safety system is effective in helping to prevent drug residues of concern in milk, even in those limited instances when medications are needed to maintain the health of dairy cattle.

- The FDA approves a drug for use in food-producing animals only when the data show there is a reasonable certainty of no harm to human health from the proposed use. When evaluating human food safety, the FDA takes into account a person’s exposure to the drug over his or her lifetime.
 - The Pasteurized Milk Ordinance requires a milk sample to be collected every time raw milk is picked up at the farm. A milk sample is also taken when a truckload or bulk tank of milk arrives at a Grade “A” dairy plant for processing. The sample from each arriving truckload of milk at the plant must be tested for the presence of at least four of six specific Beta-lactam drugs (penicillin, ampicillin, amoxicillin, cloxacillin, cephalosporin, and ceftiofur).
 - Drug residues are regulated by both federal and state food safety programs. The FDA and state regulatory officials have worked with industry to maintain high standards to help ensure the safety of the U.S. milk supply. State regulatory agencies are required to report milk testing activities to a national database, and any milk found to contain illegal drug residues is not allowed to enter the human food supply.
3. Efforts such as this sampling assignment reflect a continuous commitment to maintain the strongest possible system to ensure milk safety.
- The FDA will work closely with state regulators when considering collecting milk samples in conjunction with investigating drug residues in tissues from culled dairy cattle;
 - The FDA will utilize the data obtained from this survey to help develop the FDA’s risk ranking for drug residues in milk. This will assist the National Conference on Interstate Milk Shipments (NCIMS) in including testing for more diverse drug classes in milk as necessary; and
 - The FDA will continue to work collaboratively with state regulatory agency partners and the dairy industry to strengthen the NCIMS drug residue testing program for Grade “A” milk and to educate dairy producers on best practices to avoid drug residues in both tissues and milk.

SECTION III: Web QAs

How is milk regulated and currently tested for the presence of drug residues?

In the United States, the FDA and states partner to monitor the milk supply for drug residues under a system of oversight intended to maintain high rates of industry compliance.

The FDA collaborates with states and industry in the National Conference on Interstate Milk Shipments (NCIMS), a voluntary coalition of regulators and industry established to ensure the safety and wholesomeness of milk in the United States. The FDA publishes the Pasteurized Milk Ordinance (PMO) as a model ordinance for states to adopt.

The PMO requires a milk sample to be collected every time raw milk is picked up at the farm (also known as a “universal sample”). A milk sample is also taken when a truckload or bulk tank of milk arrives at a Grade “A” dairy plant for processing. Each arriving truckload of milk at the plant must be tested for the presence of at least four of six specific Beta-lactam drugs (penicillin,

ampicillin, amoxicillin, cloxacillin, cephalosporin, and ceftiofur). If this bulk milk sample shows concerning results, each farm that supplied milk for that truckload will undergo mandatory testing. Universal samples collected at the farm level are typically only tested if the bulk tank of milk that arrives at the processing plant tests positive for drug residues.

Why is milk tested for drug residues?

As farmers work with veterinarians to support the health of their animals, it sometimes becomes necessary to treat cows with drugs. After a cow is treated with a drug, residues of that drug may be present in milk or meat if the cow is milked or sent to slaughter before the drug is completely out of its system. If illegal drug residues are present, milk from a cow being treated with a drug cannot be sold for human consumption. Milk from road tankers arriving at dairy plants is routinely tested for the presence of certain antibiotic residues (i.e., Beta-lactam drugs) to help ensure the safety of the milk supply.

Why did the FDA conduct this sampling assignment?

The FDA collected milk samples from January through November of 2012, with the primary purpose of determining whether dairy farms with previous tissue residue violations have more drug residues in milk than other dairy farms. This type of sampling effort helps the FDA identify whether there is a problem and whether there are any steps the agency can take to further strengthen the safeguards currently in place to ensure the safety of U.S. milk supply.

How did the FDA determine which dairy farms/producers to sample?

The FDA used a risk ranking process to develop a targeted list of farms with previous tissue residue violations. Ultimately, the FDA analyzed 953 samples from targeted dairy farms and 959 control samples of milk from farms that were not included on the targeted list. In this instance, FDA investigators collected samples through the Grade "A" Pasteurized Milk Ordinance sampling system, which requires raw milk samples to be collected from each dairy farm every time milk is picked up by a bulk milk hauler.

How was this survey different from the regular Grade "A" milk sampling?

The Pasteurized Milk Ordinance (PMO), the FDA's model ordinance for Grade "A" milk and milk products production, currently only requires testing for Beta-lactam drugs. This survey was a surveillance-oriented sampling survey that looked for drug residues that are not currently included in testing under the Grade "A" milk program. Because the samples were collected in a blinded fashion, the FDA could not use any positive sample results to initiate enforcement action.

What were the results of the sampling assignment?

The milk drug residue sampling assignment revealed a very small number of samples containing drug residues of concern: 15 confirmed positive samples out of 1,912 tested, or 0.7 percent. These results are encouraging and indicate that the current system of regulatory oversight results in high rates of industry compliance.

Positive samples were found in both the group of dairy farms with previous drug residue violations (11 out of 953) and the control group (4 out of 959). While the difference in proportions of positive samples in the two study groups was not statistically significant, dairy farms with a history of a concerning drug residue in tissues were found to have confirmed drug residues from a wider variety of drugs in their milk.

What is the FDA doing in response to the findings of the sampling assignment?

In response to these findings, the FDA will:

- a. Work closely with state regulators to consider modifying testing to include collecting samples as necessary from milk tanks on farms when investigating illegal drug residues in tissues involving culled dairy cows (In current practice, the FDA investigator does not typically collect a milk sample when investigating a dairy farm as a result of a tissue residue violation); Utilize the data obtained from this survey to help develop FDA's risk ranking for drug residues in milk that will assist NCIMS in including testing for more diverse drug classes in milk as necessary; and
- b. Continue to work collaboratively with state regulatory agency partners and the dairy industry to strengthen the NCIMS drug residue testing program for Grade "A" milk and to educate dairy producers on best practices to avoid drug residues in both tissues and milk.

Is the FDA taking any regulatory action against the violators?

The goal of the study was to help the FDA prioritize its future testing efforts rather than to conduct regulatory action. Therefore this surveillance sampling assignment was blinded. It is not possible to trace back samples to any dairy farm, laboratory, or region of the country.

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

The FDA remains confident in the overall safety of the U.S. milk supply.

The FDA believes that the findings of concerning residues in just a few of the samples collected reflect a snapshot in time from a limited number of individual dairy farms and do not pose a health risk to consumers. Also, because milk from many different dairy farms is pooled together during processing, the levels of drug residues that might be present in the milk from an individual dairy producer are unlikely to result in residue levels in the pooled milk that would pose a health threat to the consumer.