

What is a “Zero Detectable” Level of a Drug and Why is it Important?

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The FDA has recently passed and enacted new regulations regarding illegal residues in meat and more stringent guidelines for certain classes of antibiotics. Included in these regulations is a new method for testing tissue samples called the multi-residue method or MRM. It is extremely accurate; it can distinguish individual chemicals even if multiple drugs are present in the same sample and boasts of faster turn-around times for results with fewer personnel requirements. It can also be validated (certified true) for specific levels of drugs called “tolerances”. This is important because the FDA establishes “tolerances” for drug residues in food animals which are the very smallest levels of a drug that will be considered acceptable if found in the meat. Tolerances are established by performing drug residue depletion studies on tissues after administering the drug or antibiotic exactly as described on the product label. This includes dose (how many cc’s), frequency (how many times administered per day), duration (how many days of therapy), route of administration (intramuscular, subcutaneous, intravenous, intramammary), and production class (bob veal, beef, dairy, steers, heifers, non-lactating dairy cattle). Many products are approved for beef and non-lactating (<20 months old) dairy cattle and, consequently, the FDA has established tolerance levels in these classes of animals. However, with a drug approved only for beef or non-lactating cattle, there is no established or acceptable tolerance level for that drug in dairy cattle, springing heifers, or dry cows. Therefore the “zero detectable level” must be reached to avoid a violative residue, no matter how tiny the amount of drug present.

What does this mean for dairy producers? It means if you are using a medication in a dairy cow that is only labeled for beef or non-lactating dairy cattle (for example: Nuflor, Micotil, Draxxin), you are using that drug in an extra-label manner. Because of this, you cannot use the meat withdrawal time printed on the label or the box as this meat withdrawal time only applies to the approved production class. The amount of time required for the detection level to reach “zero” is considerably longer and has not been measured. While the Food Animal Residue Avoidance Databank (FARAD) can give withdrawal recommendations to your veterinarian regarding extra-label use, they do not have the ability to project the “zero detectable level”. The new recommendations from FARAD generally range from a 60-90 day withholding period or more after administration of a drug that only requires 28 days to be acceptable for slaughter in a beef animal. Compounding the risk for dairy producers and veterinarians is the new methodology for drug residue screening which is far more accurate to a lower level than previously used methods.

What should you do to prevent residues?

1. Exercise extreme caution using drugs not approved for lactating cattle and consider avoiding their use altogether due to the unknown withdrawal times.
2. Only use drugs extra-label within a valid veterinary-client-patient-relationship and under the written direction of your veterinarian. Make sure withdrawal times are written and understood by all parties involved. Use a product approved for lactating dairy cows as your first treatment option.
3. Keep accurate treatment records and use an official animal identification method that is unique to the individual animal and cannot legally be tampered with or changed. Your

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written records are your best defense if accused of a residue violation. The more complete and accurate the records, the better.

4. Don't use prohibited drugs or aminoglycosides such as gentamicin in cattle. Extra-label use of the fluoroquinolones (Baytril or Advocin) is strictly forbidden. The cephalosporin class of antibiotics can only be used extra-label for a disease condition not listed on the package.
5. Do not cull recently treated cattle. Either hold the animal until she is healthy and free of drug residues or have her humanely euthanized. Remember at the slaughter facility, inspectors can order a test based on a suspicion that an animal or carcass contains residues.
6. If you are caught with a residue violation, get with your veterinarian and review the best management practices to help prevent a reoccurrence.
7. Veal producers should only use products that are approved in pre-ruminant calves. Avoid any products with the statement "not for use in calves to be processed for veal".

In summary, to prevent any type of illegal residue, the best practice is to follow label directions for all medications, vaccines, dewormers, and pesticides used on any animal intended for food (meat or milk). Work with your veterinarian when the need arises to go outside the established boundaries of approved label procedures. Keep the most accurate written records possible and use official animal identification as your best weapons to guard against false accusations of residues. Finally, do not cull recently treated animals if they do not return quickly to the productive state you were working towards. Instead, allow them time to return to a reasonable level of health and completely drug-free before culling or exercise the option to humanely euthanize her on the farm. Scrutiny of our products sent to market is only going to increase so we must have appropriate management practices in place to prevent illegal residues.