



Drug Residue Avoidance in Food Producing Animals

WHAT IS A RESIDUE?

A “residue” is any compound in edible products that results from the use of a drug in an animal that produces food. This includes the drug itself, its metabolites, and other substances formed in or on the food because of the drug’s use.

NATIONAL RESIDUE PROGRAM

The National Residue Program (NRP) is a collaborative interagency program (active participation by FDA, EPA, AMS, ARS, etc.), established to protect the public from exposure to harmful levels of chemical residues in meat, poultry, and egg products produced in, or imported into, the U.S.

WHAT IS FDA’S ROLE IN THE RESIDUE PREVENTION PROCESS?

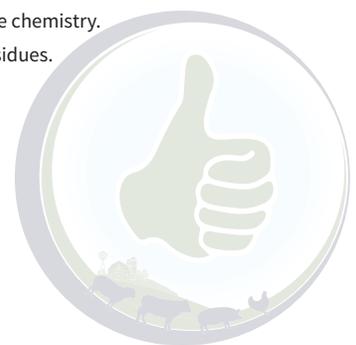
The FDA was created to assure that a product (drug or chemical compound) is safe and effective for its intended use.

FDA plays a role in ensuring that the methods, facilities and controls used for the manufacturing, processing and packaging of drug(s) are adequate to preserve their identity, strength, quality and purity.

The FDA Animal Drug Approval Process takes into consideration the following criteria when considering a product for use: Effectiveness, Target Animal Safety, Environmental Safety, Chemistry, Manufacturing and Controls, Human Food Safety and User Safety.

Animal drugs approved by FDA/CVM are evaluated for toxicology, microbial food safety and residue chemistry.

Human food safety concerns are associated with consuming edible tissues containing violative residues.





Drug Residue Prevention

RESIDUE VIOLATIONS

A result is considered “violative” when the level of residue present in the meat or edible tissue(s) exceeds tolerance levels set by FDA or the action level set by EPA. These “edible tissues” are defined as: Muscle, Liver, Kidney, Fat/Skin, Milk, Eggs and Honey.

The FDA may conduct an inspection into violations and are typically unannounced. During the on-farm inspection, everything can be inspected, with focus on how drugs are managed and used as well as how animals are managed. It is best to have all records and information ready.

Any use of a drug not specifically listed on the label is called “extralabel drug use” and is regulated by the FDA under the Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994.

Using a prescription or over-the-counter drug in an extralabel manner is prohibited unless it is a lawful order and prescribed appropriately under the guidance of a licensed veterinarian working in the context of a Valid Veterinarian-Client-Patient Relationship (VCPR) and in accordance with AMDUCA as described in 21 CFR 530 (Extralabel Drug Use In Animals).

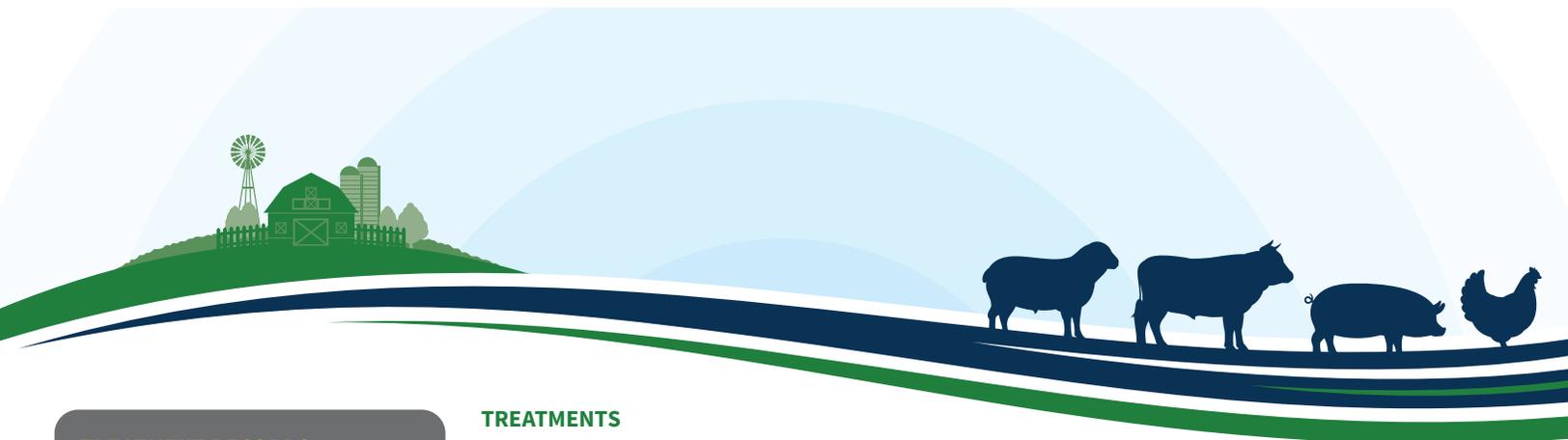


Extralabel use of medicated feed, including medicated feed containing a VFD drug or a combination VFD drug, is not permitted.

FEED ADDITIVES & MEDICATIONS

- Only FDA approved medicated feed additives should be used in feed rations.
- Any use of medicated feed additives should be in accordance with FDA Good Manufacturing Practices (GMP) regulations. This applies to both suppliers and on-farm ration formulation.
- Extralabel use of feed additives is illegal and not permitted, with limitations.
- To avoid violative residues, withdrawal times must be strictly followed. (Withdrawal times for meat are often longer than the withholding time for milk.)
- Complete records should be kept when formulating or feeding medicated feed rations.
- Producers/Operators should ensure that all additives are withdrawn at the proper time to avoid violative residues.





TREATMENT RECORDS

The following information should be recorded:

Name and Location of Facility or Farm where animal was treated

1. Tentative diagnosis
2. Name or initials of person administering treatment
3. Date(s) treated
4. Pen / Group / or Individual Identification(ID)
5. Weight of animal at time of treatment
6. Product(s) used
7. Dosage used
8. Route (IM,SQ, IV) and location of administration (ear, shoulder, neck)
9. (Withdrawal Period)Earliest date animal will have cleared milk withhold (if applicable) and meat withdrawal period
10. Outcome of treatment (animal returned to herd/culled/auction/direct to harvest)

TREATMENTS

Follow all FDA/USDA/EPA guidelines for product(s) utilized.

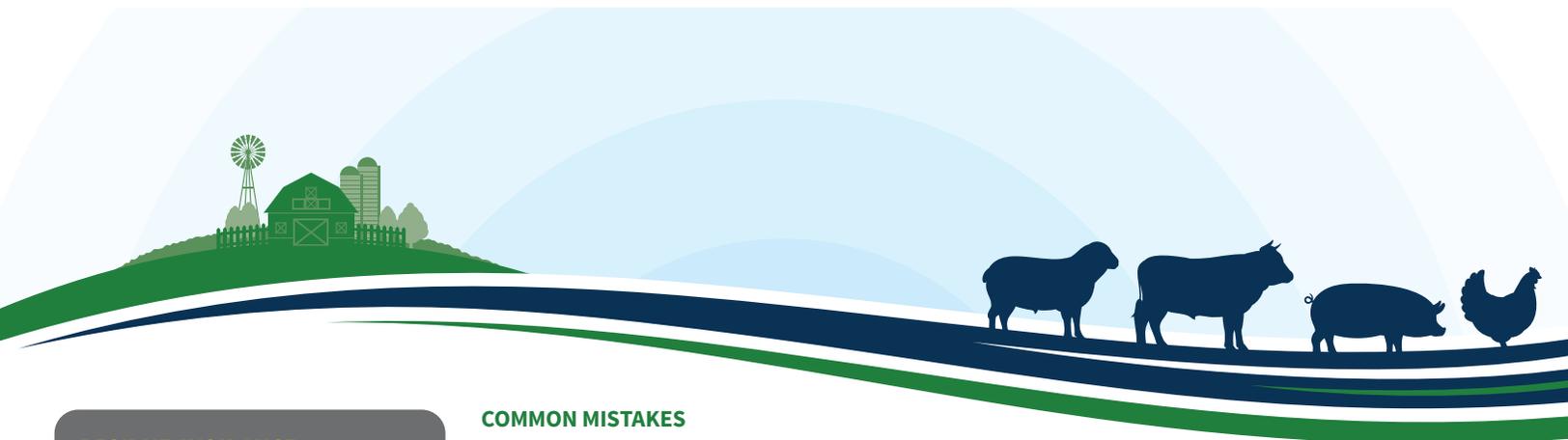
All products should be used according to label directions.

Extralabel drug use should be kept to a minimum, and used only when it is a lawful order and prescribed appropriately under the guidance of a licensed veterinarian working in the context of a Valid Veterinarian-Client-Patient Relationship (VCPR) and in accordance with AMDUCA as described in 21 CFR 530 (Extralabel Drug Use In Animals).

When Extralabel drug use is prescribed, extended withdrawal periods should be strictly followed as determined by the licensed veterinarian within the valid VCPR.

All food producing animals shipped for harvest must first be checked by appropriate personnel to ensure, but not limited to, any animals that have been appropriately treated meet or exceed label or prescription withdrawal times for all animal health products administered by the licensed veterinarian or producer.





RESIDUE AVOIDANCE

The time to consider the meat withdrawal period is before treating the animal. Meat residue violations and condemnations could be avoided by implementing and following control systems that incorporate the following segments:

1. Maintain proper individual animal identification.
2. Maintain complete records of treatments and vaccinations.
3. Properly store, label, and account for all medication(s).
4. Obtain and use animal health products only as they are labeled.
5. Maintain a Valid Veterinary-Client-Patient Relationship with a licensed veterinarian
6. Train all employees and family members about your control systems.

COMMON MISTAKES

The following are some common mistakes made when label directions on the medication(s) are not carefully followed:

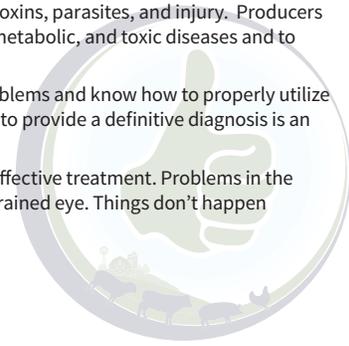
- Unless otherwise prescribed and appropriately documented by a veterinarian, any of the following actions can lead to a violative residue: treating a condition for the animal not indicated on the medication label, treating a type of animal not indicated on the medication label, incorrectly administering a medication, and using more than the dosage indicated on the medication label.
- Not following the proper withdrawal time of the medication. Often the meat withdrawal is longer than the milk withdrawal. Be aware of this when making treatment decisions on cows that have a high probability of being culled from the herd.
- Failing to clean out water and feed systems when medications are used. If it is necessary to use medications in the water and feed systems, an adequate flushing procedure should be followed and documented in on-farm feeding records.
- It is also important that medications be secured and properly stored according to label directions when not being used.
- Sometimes violative residues occur due to the improper estimation of the animal's weight at the time of treatment. This is especially important in ultimately determining the amount of medications to be administered based on label use directions.

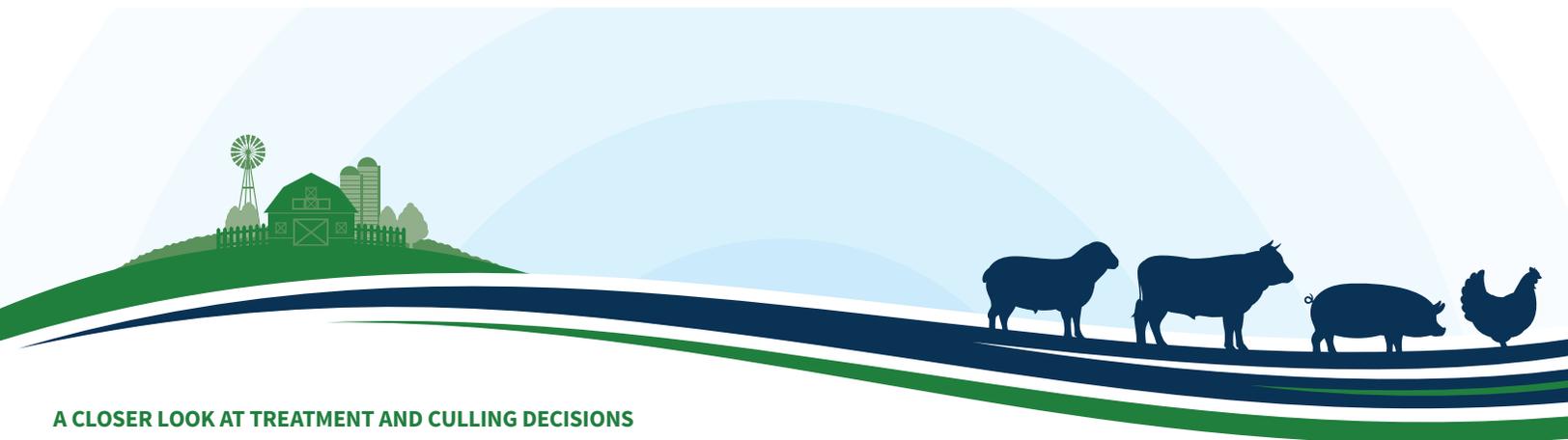
DISEASE PREVENTION PRACTICES AND HEALTH CARE — ALL AGES

All food producing animals are susceptible to infectious diseases, metabolic disorders, toxins, parasites, and injury. Producers should work with a veterinarian and /or nutritionist to determine the risk of infectious, metabolic, and toxic diseases and to develop effective management programs when designing a herd health plan.

Producers and their employees should have the ability to recognize common health problems and know how to properly utilize animal health products and other control measures. The use of a diagnostic laboratory to provide a definitive diagnosis is an effective tool for unusual or questionable cases.

Observation is a critical component for identifying health issues early and is the key to effective treatment. Problems in the herd can often arise from lack of prevention. The most important tool you have is your trained eye. Things don't happen overnight.





A CLOSER LOOK AT TREATMENT AND CULLING DECISIONS

Antibiotic use, observance of drug withhold for milk and/or withdrawal for meat, and the condition in which food producing animals are marketed from the herd/flock are human food safety issues that are managed at the farm level. Producers and their veterinarians have an obligation to consider the food producing animal's final destination when making choices about treatment.

One way to avoid marketing animals that are disabled or animals with meat residues is to evaluate health conditions early, before they get out of hand. Waiting to treat for overt signs of illness is costly and jeopardizes the health of the herd/flock as a unit.

Additionally, by delaying evaluation the producer runs a greater risk of losing the animal or losing the option of marketing the animal for human food.

GOOD TO GO!

As a producer, it is important to keep one goal in focus when growing food producing animals from farm to fork to ensure they are "Good To Go!" Providing a safe food product to the public is of the utmost importance. This can be accomplished by following the guidelines listed throughout this booklet. The major areas of focus should include, but not limited to, adequately training personnel, establishing a Valid Veterinarian-Client-Patient Relationship (VCPR) with a licensed veterinarian, always reading and following specific label-use directions on medications and medicated feed(s), maintaining complete and accurate medical treatment records for the herd and individual animals being treated, review and evaluate each element of the treatment records to assure drugs were used in approved label-directed use, and the daily implementation of control systems for food safety at your facility.

By adhering to the recommendations in this booklet and ensuring that all recommended control processes and residue prevention systems have been followed, you can be confident that any food producing animal that is offered for human consumption is "Good To Go!"

Who to contact with questions or concerns:

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REFERENCES/RESOURCES

www.nationaldairyfarm.com

Milk and Dairy Beef Drug Residue Prevention. Producer Manual of Best Management Practices 2019

www.bqa.org

qualityassurance@beef.org

303.694.0305

9110 East Nichols Avenue
Centennial, Colorado 80112

www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm380135.htm