Assuring Quality Care for Animals

Youth Food Animal Quality Assurance Curriculum Guide

GPP #1: Use an Appropriate Veterinarian/Client/Patient Relationship (VCPR) as the Basis for Medication Decision-Making

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Introduction

Assuring Quality Care for Animals is a complement to the Youth Food Animal Quality Assurance Curriculum Guide reflecting the changes in the Good Production Practices. PowerPoint presentations complement each section to assist with instruction.

Using information in this resource should help youth understand how to provide a safe, wholesome food animal product preferred by consumers.

Note – this curriculum alone does NOT certify youth for state-mandated quality assurance training. A County Coordinator or Assistant Instructor must certify youth.

Additional resources and templates referenced in this document may be found at: https://www.pork.org/pqa-plus-certification/

GPP#1
Use an Appropriate Veterinarian/Client/Patient Relationship (VCPR) as the Basis for Medication Decision-Making

Responsible medication decision-making is established through a current Veterinarian/Client/Patient Relationship (VCPR). Establishing this relationship can be a challenge for youth exhibitors. It is, however, an important step in completing the expectations of your 4-H or FFA project. This importance is based on the health of the project animal(s) as well as preventing drug residue violations, thus providing a safe and wholesome food product for consumers.

KEY TERMS:
Veterinarian/Client/Patient Relationship (VCPR)
Extra-label Use
Food and Drug Administration (FDA)
Over-The-Counter (OTC)
Prescription (Rx)
Veterinary Feed Directive (VFD)
Drug Compounding

VETERINARIAN/CLIENT/PATIENT RELATIONSHIP (VCPR)

This relationship requires that the veterinarian has seen and has knowledge of the animal and has discussed a health plan or any treatments with the owner. This relationship is required in order for a producer to use prescription drugs or a drug that is not specifically labeled for the animal (extra-label use).
A valid VCPR exists when (according to FDA regulations):

- The veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client (owner or other caretaker) has agreed to follow the instructions of the veterinarian; and when
- 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). This means the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept; and when
- The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy.

How can leaders help youth exhibitors begin to establish a VCPR?

- Have a veterinarian speak at a club or project meeting about health plans
- Bring a veterinarian along on a farm tour for the club or livestock project members

DISTRIBUTION AND USE OF APPROVED ANIMAL DRUGS

BASIC CLASSES OF DRUGS

1. Over-the-Counter Drugs (OTC): Drugs which can be purchased lawfully without a Veterinary Feed Directive or prescription
   - Producers can purchase OTC drugs and use according to the label directions when necessary. OTC drugs can be purchased from veterinary clinics, feed stores, and animal health industry representatives.
   - OTC drug labels will have exact instructions on dosage, administration, withdrawal times, and handling/storage.
   - When using OTC drugs, a producer should still consult with his/her veterinarian.
   - According to law, a producer must follow the label instructions or the written instructions by the veterinarian exactly.

2. Prescription Drugs (Rx): Drugs that require a veterinarian’s written permission for use
   - When a veterinarian prescribes a drug for use, he or she will provide a form describing use, dosage, route of administration and withdrawal times.
   - The label of a prescription drug always states “CAUTION” and “Federal law restricts use by or on the order of a licensed veterinarian.”
   - Many drugs/vaccines will say “For Veterinary use only,” but are not prescription drugs. This means that the substance is for only animal use and not human use.

What determines if a drug is labeled OTC or Rx?

- The margin of safety to the animal
- The effects on the animal from an accidental overdose
- The difficulty of identifying the disease or condition for which the drug is labeled
- The safety of the person handling and administering the drug
The Food and Drug Administration (FDA) has the responsibility of determining whether or not a drug is OTC or Rx

**TYPES OF DRUG USE**

1. **Label Use**: Using the drug EXACTLY as stated on the label.
   - Medicated feeds may only be used as directed by the label.
   - It is **ILLEGAL** for a producer or veterinarian to use a medicated feed in a manner other than is directed by the label.

2. **Off Label**: Use of a drug by a producer in a manner other than what is stated on the label and without guidance from a veterinarian under the extra-label policy.
   - It is **ILLEGAL** to use an OTC drug for anything other than intended unless directed by a licensed veterinarian.

3. **Extra-Label**: Extra-label drug use means using an animal drug in a manner not in accordance with the approved drug labeling.
   - When labeled drugs are not available to maintain adequate animal care, a veterinarian has the ability to prescribe extra-label drug use.
   - Only a veterinarian with a valid Veterinarian/Client/Patient Relationship (VCPR) for the operation can direct extra-label drug use.
   - The following are examples of extra-label drug use:
     - Increasing the dosage from the recommended label dosage
     - Changing the frequency or the route of administration
     - Changing the duration of treatment
     - Treating for a disease or condition not listed on the label
     - Treating a species of animal not listed on the label
   - The producer and veterinarian accept added responsibilities when using drugs in an extra-label manner.
     - Make sure a medical diagnosis has been made by the veterinarian
     - Verify that adequate directions for use have been provided and will be followed
     - Follow extended drug withdrawal times so no violative levels of residues remain in the animal
     - Maintain identity of all treated animals for the extended withdrawal time
   - Extra-label drug use under the direction of a licensed veterinarian is used in livestock production when alternatives are not available.
   - This is most common with species such as sheep, goats, and rabbits because few drugs are FDA approved, as a result of cost, for use in minor species.

**When an OTC product is used in an extra-label manner the requirements are as follows:**

- A VCPR exists.
- Adequate instructions have been given by the veterinarian and are followed by the caretaker.
- A withdrawal time has been assigned by the veterinarian so the extra-label drug use does not result in a violative residue.
- Identity of the treated animal is maintained.
The treatment is recorded, and the records are maintained by the producer for at least one year after the animal is treated. The veterinarian must keep these records for two years.

According to the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), FDA has the authority to prohibit the use of certain drugs in food producing animals. Certain drugs are not labeled for use in a specific species and may be prohibited for use in an extra-label manner in that species by the FDA. If in question, use OTC products as intended.

VETERINARY FEED DIRECTIVE (VFD)
The VFD is a category specifically for new antimicrobial drugs used in the feed to treat disease.

✓ **Antimicrobial** – A drug used to treat a microbial infection.

✓ A producer may not buy VFD products and store them on the farm unless he or she meets one of the following criteria:
  - Holds a valid feed mill license
  - Is a distributor of VFD feeds
  - Has a valid VFD issued by a veterinarian

✓ Extra-label use is not permitted.

COMPOUNDING OF ANIMAL DRUGS
(Adapted from the NPB PQA Plus 2013)
Mixing two injectable FDA approved drugs together in a bottle or syringe is called compounding. This is necessary in some cases to fit the specific needs of some patients in order to assure recovery. Withdrawal times are of concern as interactions of different components can result in the formation of new compounds, case destruction, and/or precipitation of active or inactive ingredients. According to the AMDUCA, a veterinarian with a VCPR may be permitted to compound FDA approved drugs following guidelines similar to extra-label drug use. It is illegal to use a compounded drug without a veterinarian’s professional opinion determining the safety, efficiency and withdrawal time.

DRUG RESIDUE AVOIDANCE AND TESTING
Identification and documentation of all treated animals will reduce the chance for a drug residue to enter the food chain. This will require that exhibitors are diligent in recording and maintaining an accurate log or record book of medical and therapeutic treatment of each animal. The producer, parent/guardian, and exhibitor have a responsibility for producing a safe and wholesome food product. When an animal or food product is marketed, the seller should be confident that no drug residue exists based on an accurate record system. If a person is unsure, then a drug residue test can be conducted. Severe consequences for producers and youth exhibitors are enforced when drug residues are found. Ignorance is not a defense if a residue is determined in a food product from a youth’s project animal.
RESIDUE
✓ Presence of a drug in an animal product or by-product
✓ Any substance that is prohibited under any federal or state law
✓ Any drug used in any manner not authorized under any federal or state law
✓ What could cause a drug residue in milk or meat?
  o Poor animal identification
  o Treatment not recorded
  o Not following label directions
  o Extra-label drug use
  o Feeding of medicated feed
✓ What animals might be considered high risk for drug residue?
  o Cull breeding animals
  o Animals that have received an extra-label medication prescribed by a veterinarian
  o Young animals such as veal calves or feeder pigs sold as roasters
  o Animals exhibited at shows or fairs

DRUG RESIDUE TEST
✓ A drug residue test can be conducted by a veterinarian and sent to the Ohio Department of Agriculture for analysis
✓ Can be performed before an animal is marketed to ensure a safe food product
✓ Drug residue tests are routine on fair or exposition animals
✓ If a drug residue is found in meat or milk, the product will be condemned (thrown away, unfit for human consumption)
✓ Producer/youth exhibitor could be:
  o Subject to a fine
  o Prohibited from selling livestock and/or food products
  o Prohibited from showing animals at other exhibitions
✓ For example:
  If a dairy cow’s milk contains drug residues and the milk is put into the bulk tank with the rest of the herd’s milk, then all of the milk from that dairy herd would be condemned, as well as any milk from other producers that came in contact with the contaminated milk.
✓ A drug residue test can:
  o Save money
  o Ensure safety and quality of animal food products
  o Enhance the reputation of youth livestock programs

REGULATORY AGENCIES RESPONSIBLE FOR DRUG RESIDUE LIMITS AND TESTING:
✓ Food and Drug Administration (FDA): Responsible for regulating medicated animal feed and most animal health products. The FDA approves the product, sets residue tolerance or action levels in edible tissues, and determines how drugs are to be administered in animals.
United States Department of Agriculture (USDA): Division of the federal government that enforces regulations related to agriculture

Food Safety and Inspection Service (FSIS): Division of USDA and inspects all food products from animals in federally inspected packing plants and food processing facilities and examines plant sanitation. The FSIS conducts both routine residue monitoring and targeted food safety surveillance activities.
  - Routine testing is conducted on randomly selected carcasses to detect tissue residues that exceed maximum levels allowed
  - Targeted testing is directed toward herds or populations of animals (such as fair animals) with a history of violations or where there is some reason to suspect there could be violative tissue residue, such as visible injection sites in the muscle at marketing

Ohio Department of Agriculture (ODA): Division of the state government that enforces Ohio regulations related to agriculture

Use an Appropriate Veterinarian/Client/Patient Relationship (VCPR) as the Basis for Medication Decision-Making Study Questions

1. What does VCPR stand for?
2. What are your responsibilities in a VCPR?
3. What are three benefits of having a VCPR?
4. How is your veterinarian vital to the medication decision-making process?
5. Describe the three categories of approved drug distribution.
6. How is extra-label drug use defined?
7. What is drug compounding?
8. What are the risks of drug compounding?
9. What animals might be considered high risk for drug residue?
10. Identify three residue avoidance practices.