Beef Quality Assurance℠

ANTIMICROBIAL STEWARDSHIP FOR BEEF PRODUCERS

BEEF

Funded by the Beef Checkoff

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A Beef Producers Guide for Judicious Use of Antimicrobials in Cattle

Cattle producers are committed to antimicrobial stewardship and promotion of judicious use of antibiotics. Responsible antimicrobial stewardship is important to ensure that animal health technologies, including antibiotics and antiparasitics, remain viable for cattle raisers and care givers. These guidelines are intended to support responsible antimicrobial use in the cattle industry, using preventive health programs as outlined in the BQA program and under the oversight of the herd veterinarian.

1. **Prevent Problems:** Emphasize appropriate husbandry, hygiene, biosecurity, routine health examinations, nutrition, and vaccinations to prevent animal health concerns and reduce the need to use antimicrobials. Train cattle caretakers to recognize and diagnose issues early for better outcomes. Work with your herd veterinarian to design prevention and training protocols to maintain animal health and welfare.
2. **Adhere to FDA guidance:** Follow label instructions and FDA guidance for the use of all antibiotics and animal health products. The use of antibiotics medically important in human medicine should be used only after careful consideration with your veterinarian. If medically important feed grade antibiotics are used, they must be under the guidance of a Veterinary Feed Directive (VFD). There is no allowed extra label use of feed grade antibiotics.
3. **Select and Use Antibiotics Carefully:** Using a valid Veterinarian-Client-Patient-Relationship (VCPR), consult with your veterinarian on the selection and use of antibiotics including post-treatment intervals and drug rotation. Veterinarians may elect to use a diagnostic test such as culture and susceptibility to aid in selection. Have a valid reason to use an antibiotic. Appropriate preventive and therapeutic alternatives should be considered prior to using antimicrobial therapy.
4. **Combination Antibiotic Therapy Is Discouraged Unless There Is Clear Evidence the Specific Practice Is Beneficial.**
5. **Avoid Inappropriate Antibiotic Use:** Limit therapeutic antibiotic use to proven clinical indications, avoiding inappropriate uses, such as for viral infections without bacterial complication.
6. **Treatment Programs Should Reflect Best Use Principles:** Regimens for therapeutic antimicrobial use should be optimized using current pharmacological information and principles. Follow your veterinarian's instructions including treating for the recommended dosage, route of administration, time frame, and following withdrawal times.
7. **Treat the Fewest Number of Animals Possible:** Limit antibiotic use to sick or at-risk animals. The use of antimicrobials should be based on an evaluation of animal-specific risk factors for disease.
8. **Properly Dispose of Animal Health Products:** Follow all applicable local, state, federal, and Tribal regulations and guidelines for disposal of pharmaceutical waste. Never pour or flush products down drains or toilets nor burn waste unless permitted by authorities. Expired medications should not be used.
9. **Keep Records of Antibiotic Use:** Accurate records of treatments and outcomes should be used to evaluate efficacy of therapeutic regimens. Always follow proper meat and milk withdrawal times. Keep records for a minimum of 2 years or longer based on state and local regulations.
10. **Follow Label Directions:** Follow label instructions and never use antibiotics other than as labeled without a valid veterinary prescription. Handle and store animal health products according to label instructions.
11. **Extra Label Antibiotic Use Must follow FDA Regulations:** Prescriptions for extra label use of medications must meet the Animal Medicinal Drug Use Clarification Act (AMDUCA) amendments to the Food, Drug, and Cosmetic Act and its regulations. This includes having a valid VCPR and exaggerated withdrawal time.
12. **Medically Important Antibiotic Use Should be Limited to Treat, Prevent or Control Disease:** Antibiotics that are medically important to human medicine cannot be used to improve performance. Veterinary oversight of antimicrobial use should be based on clinical and epidemiological knowledge.

Guidelines developed from AVMA, AABP and AVC guidance on Appropriate Veterinary Antibiotic Use

INTRODUCTION TO ANTIMICROBIAL STEWARDSHIP

The Beef Checkoff-funded Beef Quality Assurance (BQA) program sets in the forefront of what we do as beef producers, and it serves as the path for sustainability in producing high quality and wholesome beef that consumers are proud to enjoy at the center of their plate. The program provides cattle producers with the educational resources to promote continuous improvement with the mindset of doing things the right way at the right time. Supporting all sectors of the cattle industry including cow-calf operations, dairy farms, grazing operations, cattle-feeding operations, and more, BQA guidelines can be integrated into any cattle care program.

BQA provides the backbone for cattle care and management practices. These BQA guidelines are grassroots-based, voluntary, and backed with science, education, and certification. The program provides a foundation for the beef industry to share producers' and veterinarians' commitment to continuous improvement and responsible cattle management. BQA has met internationally-recognized animal welfare standards set forth by the World Organization for Animal Health, continuing that commitment to high standards of care.[1]

Responsible antimicrobial stewardship is important to ensure that animal health technologies remain viable options for better disease management. Antimicrobial stewardship applies to all animal health products, including approved antibiotics, antiparasitics, antifungals, and antivirals. Cattle producers and caretakers should understand preventive strategies that minimize disease risk, including husbandry, biosecurity, routine examinations, and vaccination.

Working with a herd veterinarian and resource group to develop operation-specific protocols can improve management, record keeping, and provide employee training opportunities. The veterinarian-client-patient relationship (VCPR) is a key piece to improving animal health and tailoring care decisions for the herd.

The judicious use of antibiotics, antiparasitics, and other medicines is a responsibility of all cattle caretakers and benefits the animal, consumer trust, and the business' bottom line. When healthy cattle leave the farm and reach the marketplace, the producer, packer, and consumer all benefit. When better quality beef reaches the supermarket, consumers are more confident in the beef they are buying, and this increases beef consumption.

1. USDA Agricultural Marketing Service. 2024. International Organization for Standardization (ISO) Technical Specification (TS) 34700 - Animal Welfare Management/General Requirements and Guidance for Organizations in the Food Supply Chain. *www.ams.usda.gov/services/auditing/awap*

ANTIMICROBIAL CLASSES AND CATEGORIES

Antimicrobials are medicines used to prevent, control, and treat infections caused by microorganisms. Different types include:

- Antibiotics: Therapy against bacteria.
- Antivirals: Therapy against viruses.
- Antifungals: Therapy against fungi.
- Antiparasitics: Therapy against parasites such as dewormers or parasite control.

Responsible use of all U.S. Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and U.S. Department of Agriculture (USDA) approved animal health products is critical to animal health and welfare and food safety.

Categories of animal health products include Over-the-Counter (OTC), Prescription (Rx), and Veterinary Feed Directive (VFD).

- **OTC** products do not require a veterinary prescription for purchase or use but cannot be used extra-label unless directed by a veterinarian. Many antibiotics that were previously available OTC have transitioned to prescription only. Not all OTC products are allowed for use in food producing animals. Read the label and consult with the herd veterinarian before use.
- **Rx** drugs require a valid VCPR and are restricted by federal law to use by or on the order of a licensed veterinarian. These include medically important antibiotics and soluble (water-based) medications. It is illegal to use prescription drugs in an extra-label manner, unless specifically prescribed by a veterinarian.
- A **VFD** requires a valid VCPR and is required for any medically important antibiotic that is administered via feed in any food animal species. It is illegal to use any VFD drugs in an extra-label manner.

VETERINARIAN-CLIENT-PATIENT RELATIONSHIP (VCPR)

Veterinarians are trained to evaluate individual and groups of animals within a herd system and provide integrative management plans to prevent diseases or problems from occurring in the future.

A VCPR is necessary for veterinary oversight of animal health and welfare and proper animal health product use on livestock operations. It is legally defined by state and federal statutes as well as by the American Veterinary Medical Association (AVMA). An established VCPR allows the veterinarian to diagnose animals, prescribe medications and drug therapy to treat, control, or prevent disease, and issue Certificates of Veterinary Inspection (CVIs) or health certificates. Residue avoidance in meat and milk products is a team effort that starts with the VCPR. Written and signed VCPRs are recommended for record keeping.

VCPRs should be renewed annually, based on state or federal guidelines. Schedule a yearly consultation with your veterinarian to review current practices and to develop and set goals for the next year and consider areas for improvement.

A valid VCPR is required for producers to use all prescription medications, extra-label use of nonprescription medications, and all FDA feed medications that require a VFD. Important elements of a VCPR[2] include the following.

- A veterinarian has assumed the responsibility for making medical judgments for the animal's health and the need for medical treatment, prevention, or control of disease.
- The client (owner of the animal(s) or other caretaker) has agreed to follow the instructions of the veterinarian.
- The veterinarian has sufficient knowledge of the animal(s) to provide a general or preliminary diagnosis of the medical condition of the animal(s); the veterinarian has recently seen and is familiar with the care of the animal(s) through physical examination(s) or medically appropriate and timely visits.
- The practicing veterinarian assumes responsibility for follow-up care, including adverse reactions and/or therapy failure. Such a relationship can exist only when the veterinarian has recently seen and is familiar with the keeping and care of the animal(s) through physical exams and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.
- Veterinarians regularly evaluate medication and therapy records with cattle producers to review response to therapy and protocol compliance including medication withdrawal compliance. Ensuring written or electronic treatment records of treated animals or groups of animals is important to preventing residues.

BQA collaborates with the AVMA, American Association of Bovine Practitioners (AABP), and Academy of Veterinary Consultants (AVC) in establishing and providing animal health and welfare guidelines. Additional VCPR considerations for veterinarians and other guidelines can be found at their websites.

AVMA Resources & Tools

AABP Guidelines and Position Statements

2. Extralabel Drug Use in Animals, 21 C.F.R. § 530.3 (2024). *https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part- 530/subpart-A*

PREVENTING RESIDUES FOR FOOD SAFETY

Animal health products are approved by FDA, USDA, or EPA depending on the product after evaluation for safety and efficacy. For food-producing animals like cattle, there is an additional food safety requirement the agency must complete to prove the use of the product does not present a risk to human health. There are many safeguards in place to optimize animal health and improve food safety including following withdrawal times. Withdrawal times for all veterinary drugs, including antibiotics, vaccines, and dewormers, are set by the agency approving the product.

The FDA approves veterinary drugs and the specific dosage rates to treat specific diseases or conditions. EPA has specific labels and regulations for each topical antiparasitic. USDA approves vaccines and other veterinary biologics for animals used for food production.

Farmers, ranchers and veterinarians are required by law to follow the FDA/EPA/USDA-approved label to administer the drug appropriately and correctly. Animal health companies must prove that their veterinary drugs are safe and effective for the intended animal patient, much like the drug approval process for human antibiotics and products.

A residue refers to the presence of veterinary drugs or pesticides in meat. These residues are usually measured in parts per million or parts per billion.

The overwhelming majority of meat products contain no residues or residues within the government prescribed tolerance levels. Veterinary drug tolerances are established by the FDA under the Federal Food, Drug and Cosmetic Act. EPA establishes tolerances for registered pesticides under the Food Quality Protection Act.

The FDA approves veterinary drugs and the specific dosage rates to treat specific diseases or conditions. Farmers, ranchers and veterinarians are required by law to follow the FDA-approved label to administer the drug appropriately and correctly. Animal health companies must prove that their veterinary drugs are safe for the intended animal patient and effective for the condition treated, much like the drug approval process for human antibiotics.

The prevention of illegal or violative drug residues in meat and milk products is a continuous, coordinated effort between government agencies, veterinarians, and livestock producers that begins before the drug is ever used in animals. The drug approval process, on-farm antibiotic use measures, and the U.S. National Residue Program are all specifically designed to prevent animal products with illegal drug residues from entering the food supply.

The FDA/EPA/USDA also sets withdrawal times for all veterinary drugs, including antibiotics, dewormers, and vaccines. The withdrawal period is the time between the last dose of the antibiotic medication and the time when the animal can be safely slaughtered for food (or, with dairy cattle, the milk can be safely consumed). Practically, the withdrawal time is the amount of time required for the drug to be reduced to a safe tolerance level. The withdrawal time depends on the drug, but typically ranges from zero to 60 days. Read the label or work with your veterinarian to confirm withdrawal times.

Withdrawal Time: The time that must pass between the last dose of an animal health product (vaccine, antibiotic, dewormer, or other) given and when it is safe and legal to harvest the animal or its products (like milk). If multiple animal health products are administered at the same time, the withdrawal time will be based on the product with the longest withdrawal period.

- The animal will metabolize the product in this time frame and then it is safe to enter the public food supply.
- All FDA approved products in food-producing animals have labeled meat and milk withdrawal times that caretakers are legally required to follow. The labeled withdrawal time only applies if the drug is used according to label directions.
- Work with the herd veterinarian to confirm and record withdrawal times, especially for any off-label use. Keep records of all treatments.

The final step in protecting and preventing illegal antibiotic residues from entering the food supply is surveillance testing conducted by the USDA Food Safety Inspection Service (FSIS). The agency conducts tests for chemicals—including antibiotics and various other drugs, pesticides, and environmental agents—in meat, poultry, and egg products destined for human consumption. The surveillance program consists primarily of two tiers of testing: scheduled and inspector generated.[3]

Scheduled antibiotic residue testing is pre-planned to provide a large sample across different food animal industries (beef cattle, veal calves, swine, poultry, dairy, etc.) and locations. Not all tests will detect all residues. For instance, testing urine may not detect a kidney that will test positive by the USDA-FSIS. The development of scheduled sampling plans is a process that proceeds in the following manner:

1. Determine which compounds are of food safety concern;
2. Use algorithms to rank the selected compounds;
3. Pair these compounds with appropriate production classes; and
4. Establish the number of samples to be collected.

Inspector generated samples are collected from animal carcasses that show signs of previous disease or medical treatments—animals that may present an above average risk for illegal antibiotic residues. In the rare cases when an illegal drug residue is confirmed, the beef product is considered "adulterated" and is never allowed to enter the food supply. The USDA and FDA then initiate a cooperative effort to investigate the reasons for the illegal use. Depending on the severity of the residue, the intent and history of the violations, the investigation may lead to a variety of outcomes for the animal owner, from a warning letter to injunction to criminal prosecution.

3. U. S. Department of Agriculture Food Safety and Inspection Service. 2024. Ante-Mortem Livestock Inspection. *https://www.fsis.usda.gov/policy/fsis-directives/6100.1*

The FSIS Hazard Analysis Critical Control Points (HACCP) program implemented at slaughter facilities identifies the animals most likely to have drug residues. Animals that display lameness, injection site lesions or signs of illness during antemortem inspection are targeted for testing. If there is any doubt about the potential for drug residues in an animal, they should be withheld from market.

Producers who market animals that test positive for chemical residues more than a single time will be placed on the publicly available USDA FSIS Residue Repeat Violator List.

FSIS maintains a "Repeat Residue Violator List for Use by FSIS Inspection Personnel" that contains the names and addresses of animal suppliers, including producers, operations, auction markets, and others, who have more than one meat residue violation in a rolling 12-month period in animals presented for slaughter. Specific information about the violation can also be found in this list, including the plant where the violation was determined, the drug residues discovered, and their concentrations and tolerances. Violators listed may have had multiple violations documented in the same processing facility or separate facilities. This list is intended to aid inspectors and slaughter establishments in discovering residue tolerance violations before they reach consumers. FSIS provides a user guide that explains the information contained in the list.

FSIS also maintains a "Residue Repeat Violator List for Use by Livestock Markets and Establishments" that contains similar information intended to assist establishments and livestock markets in identifying residue history of livestock suppliers. This second list documents only the source name and address information of repeat violators, so that livestock marketers and buyers may use precaution when marketing and processing animals from listed suppliers.

VETERINARY FEED DIRECTIVE (VFD)

The FDA requires a VFD for all feed-use antibiotics that could potentially impact human antibiotic resistance. If a cattle producer needs to use a VFD feed medication, they must obtain the VFD from their veterinarian with which they have a VCPR. The veterinarian must be licensed to practice in the state in which the cattle are located. The only FDA approved VFD feed medications are those used for treatment or control of specific diseases. The longest duration any VFD can have is 180 days unless specifically limited by the label.

There are no FDA approved VFD medications for treatment, control, or prevention of footrot or pinkeye. It is a violation of federal law to use any FDA approved feed medication other than as approved by the FDA. All VFD records must be kept and be available for inspection for two years by the issuing VCPR veterinarian, the cattle producer, and the feed mill distributing the VFD medication.

There are several FDA approved feed medications that do not require a VFD. However, if used in feed at the same time as a VFD drug, that concurrent use must be authorized and approved on the VFD. Notable among these are ionophores and parasite control medications. Visit with your veterinarian for more detailed information.

Feed Manufacturers
An important responsibility of a feed manufacturer is to assure that the feed produced — whether medicated or non-medicated — meets all legal and intended specifications.[4] All feed mixing operations, regardless of size or products used, share this responsibility.

In-feed drugs are divided into two categories:

- CATEGORY 1: Drugs that have no required withdrawal time when used at lowest usage level.
- CATEGORY 2: Drugs that either have withdrawal times at lowest usage level or are regulated because of a “no residue” tolerance level.

All medicated feeds are divided into three types:

- TYPE A: Medicated articles that usually consist of highly concentrated forms of the drug in the form of mill premixes, super-concentrates, and fortifiers that have a higher potency than permitted in Type B or Type C feeds. Type A articles are used to produce Type B and Type C feeds. Type A medicated articles may be purchased without a VFD but must have a VFD to feed them in the form of a Type C feed. It is illegal to feed a Type A medicated article as a top dress.
- TYPE B: Medicated feeds that consist of diluted drug premixes, some feed concentrates, supplements, and other mixtures that require further mixing with one or more feed ingredients to achieve final dilution before being fed as a Type C medicated feed. Type B medicated feeds may not be fed directly to the animal without incorporation into a Type C medicated feed.
- TYPE C: Medicated feed in its final form that does not require any additional dilution prior to being fed. Type C medicated feeds may be top dressed, fed as a complete feed, or fed as a free choice feed. In order to be fed as a top dress or as a free choice feed, the Type C feed must be specifically approved for this application.

Feed manufacturers must register with the FDA. If mixing a medicated feed containing a VFD drug and selling this complete feed to another entity (such as another operation), the business is considered a feed manufacturer and must adhere to FDA regulation.

Combining the use of different feed medications must be approved by the FDA. Medication manufacturers are also a reliable source of information regarding combining medications they make with medications from other sources.

4. FDA 21 C.F.R. § 558.3 (2024). *https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-558/subpart-A/section-558.3*

HERD HEALTH PROTOCOL DEVELOPMENT

Working with a herd veterinarian and resource group to develop operation-specific protocols can improve management, record keeping, and provide employee training opportunities. Sample protocols can be found at *www.bqa.org*. Producers and their employees should have training to recognize common health problems and know how to properly use animal health products and other control measures. When prevention or control measures are ineffective, the producer should promptly contact a veterinarian for diagnosis and treatment to reduce animal suffering and animal losses.

Each operation should customize their herd health plan with the herd veterinarian. Key BQA guidelines to consider include the following.

- Review diagnosis and therapy protocols at least annually with the herd veterinarian. Train employees and use self-assessment tools to ensure disease diagnosis and therapy are appropriate.
- Keep management and therapy protocols on file and at the treatment facility where workers can review them.
- Updates should have the veterinarian's signature or initials and date when the protocols are reviewed.
- Any medication that requires use other than as directed on the label must have revised administration procedures and withdrawal time included in the management and treatment protocols.
- Per state-specific regulations, ask suppliers to attach revised use labels obtained from the herd veterinarian to each product delivered. These labels must include the veterinarian's name, address, phone number, revised directions for use, and withdrawal time. Having all product withdrawal times listed in a treatment or animal health protocol book is a best management practice.
  - All vaccines have a withdrawal time (21 days for non-oil adjuvant or water-based vaccines and 60 days for oil adjuvant vaccines). Always read the label for each product's withdrawal time.
- Develop a follow-up plan and/or alternative treatments if the initial treatment does not produce the desired result.
- Pain management should be considered at all stages of cattle production. Although there are very few FDA approved anesthetics or analgesics (pain medications) for cattle, veterinarians can design pain management protocols and prescribe pain management medications. Producers must follow the veterinarian's instructions for all drug use, including ELDU, following extended withdrawal times, maintaining records, and identifying treated animals.
- Market animals only if all drug withdrawal times are met and the animals are fit for transport.

Prescription or Veterinary Drug Orders (VDO)

A Prescription/Veterinary Drug Order (VDO) is a veterinarian-approved list of medications used on the operation that is issued to authorized veterinary supply companies or pharmacists to dispense supplies to an operation. For example, the veterinarian may send in a VDO to an online vet supply company. Discuss with the herd veterinarian other products or supplements that fit the herd's care plan.

State laws will determine how often a VDO needs to be reviewed and renewed. A veterinarian may need to specify brand name as well as the generic name on the VDO because the drug withdrawal time and route of administration may be different for similar medications and vaccines. Only the herd veterinarian may change or update the VDO.

Animal Medicinal Drug Use Clarification Act (AMDUCA) and Extra-Label Drug Use (ELDU)

Veterinarians can prescribe ELDU (or off-label use) of certain approved new animal drugs and approved human drugs for animals under certain conditions (when health of animal is threatened or failure to treat may result in suffering or death). Under the AMDUCA regulations, any extra-label use of an approved new animal or human drug must be by or on the lawful order of a veterinarian within the context of a VCPR.[5] Treatment or animal health records including withdrawal times are critical.

ELDU, or off-label use, is defined as but not limited to using a drug in the following ways:

- at a dose not listed on the label.
- by a different route not listed on the label.
- for a condition or indication not listed on the label.
- in a different frequency and duration not listed on the label.
- in a species not listed on the label.

Veterinarians use a university-based resource called the Food Animal Residue Avoidance Databank (FARAD, *www.farad.org*) to calculate scientifically based recommendations for safe withdrawal intervals of drugs and chemicals in food-producing animals.

Food Animal Residue Avoidance Databank (FARAD)

FARAD is a national, USDA-sponsored, cooperative project, with a primary mission to prevent or mitigate illegal residues of drugs, pesticides and other chemicals in foods of animal origin. Producers should work with the veterinarian with whom they have a valid VCPR for drug residue information first. The veterinarian is the ideal resource to discuss FARAD-specific information regarding withdrawal times, especially for extra-label drug use.

FARAD provides the following services:

- Advice on residue avoidance or mitigation
- VetGram search for required withdrawal times for approved food animal drugs
- FARAD-recommended withdrawal intervals for extra-label use of approved food animal drugs

5. U. S. Food and Drug Administration. 2024. Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). *https://www.fda.gov/animal-veterinary/guidance-regulations/animal-medicinal-drug-use-clarification-act-1994-amduca*

Altering any FDA approved animal drug's original packaging or formulation is considered adulteration by the FDA.

Under certain circumstances, FDA can prohibit extra-label uses of certain drugs in animals. Drugs (both human and animal), families of drugs, and substances prohibited from extra-label uses in all food-producing animals are seen in the box below. Following veterinary protocols to reduce risk of using these medications.

Drugs Prohibited for ELDU in Food-Producing Animals

- Chloramphenicol
- Clenbuterol
- Diethylstilbestrol
- Fluoroquinolone antibiotics
- Glycopeptide antibiotics
- Nitroimidazoles (Dimetridazole, Ipronidazole, Metronidazole)
- Nitrofurans (Furazolidone, Nitrofurazone)
- Phenylbutazone (female dairy cattle >20 months old)
- Sulfonamides (lactating dairy cattle or dairy cattle >20 months old)
- Cephalosporins may be used for an off-label indication in major food animal species, but regimen cannot be altered. One exception is cephapirin, an intramammary first generation cephalosporin. These cephalosporin ELDU prohibitions do not apply to minor food animal species.

Aminoglycoside Use in Cattle

Aminoglycoside antibiotics (e.g., neomycin, gentamicin, kanamycin) should not be used in cattle, except as specifically approved by FDA. This is supported by the cattle veterinarian organizations AABP and the AVC because these have historically been a top residue cause in cattle.

The BQA program does not support the ELDU of aminoglycosides because of the extremely long withdrawal (over two years) and the potential for a violative residue.

COMPOUNDING

Compounding is the combining, mixing, or altering ingredients of a drug product beyond what is described on the product label. Compounding of medications to treat cattle and other food-producing animals by a veterinarian is strictly regulated.[6] Using compounded medications is considered ELDU. The AMDUCA regulations state that compounded preparations are required to be prepared from FDA approved animal or human drugs and that, if possible, an animal-labeled drug is to be used for compounding rather than a human-labeled drug.

Never mix two antibiotics, two vaccines, or other products in one syringe. An undesired chemical reaction may occur, destroying each product's effectiveness, causing a painful injection that can result in a larger tissue lesion, and unknown safe withdrawal times. This could be considered compounding, which only veterinarians can decide.

The veterinarian must calculate or recommend a withdrawal interval for any compounded or ELDU product. If there is not sufficient data to establish a withdrawal interval, then the veterinarian must assure that the animal and its products never enter the food chain. Overall, compounding for food animals should be rare. When treating an animal whose tissues or products have the potential to enter the human food chain, it's important to remember that food safety and public health come first.

JUDICIOUS USE OF ANIMAL HEALTH PRODUCTS

Antimicrobial stewardship refers to practices that livestock producers and veterinarians take to preserve availability and effectiveness of antimicrobial drugs through conscientious veterinary oversight and responsible medical decision-making. These actions help safeguard animal, public, and environmental health. Preventive health guidance in areas like husbandry, biosecurity, routine examinations, and immunization are integral to improving antimicrobial stewardship, which BQA fully supports. Antimicrobial stewardship applies to all classes, though particular emphasis on antibiotics and antiparasitics has been shown in the livestock industry.

Antimicrobial resistance happens when bacteria, viruses, fungi, or parasites change over time and resist the effects of antimicrobials, which are designed to kill the microorganisms. Drugs that were once effective become less effective at treating infections, leading to health and welfare concerns for both humans and animals. Antimicrobial resistance poses a threat to disease control throughout the world and is a primary concern for human and animal health.

6. Extralabel use from compounding of approved new animal and approved drugs, 21 C.F.R. § 530.13 (2024). *https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-530/subpart-B/section-530.13*

The FDA's Center for Veterinary Medicine requires increased veterinary oversight for use of medically important antibiotics that are important in human medicine and have a valid use in animals.[7,8,9] This guidance supports judicious use of antibiotics by removing the use of medically important antibiotics for growth purposes (which has been illegal in the U.S. since 2017), transitioning over-the-counter medically important antibiotics to veterinary prescription, and promoting the partnership or the VCPR between a veterinarian and the cattle producer.

Following the judicious antimicrobial use guidelines (page 3) and medication use protocols developed for the BQA program is critical so that cattle are responsibly treated and are never marketed with violative residues. Marketing cattle with a violative residue, even unintentionally, is illegal and can result in significant consequences — both legally and financially.

Antiparasitics such as dewormers, fly tags and other parasite controls are important and useful tools for the cattle industry, however, parasite resistance to antiparasitics is becoming more common. Parasite management varies by region with differences in climate, environmental conditions, host susceptibility, and farm/ranch management practices.

7. Center for Veterinary Medicine. (2012, April). The judicious use of medically important antimicrobial drugs in food-producing animals. (GFI #209). Food and Drug Administration. *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-209-judicious-use-medically-important-antimicrobial-drugs-food-producing-animals*
8. Center for Veterinary Medicine. (2013, December). New animal drugs and new animal drug combination of products administered in or on medicated feed or drinking water of food-producing animals: Recommendations for drug sponsors for voluntarily aligning product use conditions with GFI #209. (GFI #213). Food and Drug Administration. *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-213-new-animal-drugs-and-new-animal-drug-combination-products-administered-or-medicated-feed*
9. Center for Veterinary Medicine. (2021, June). Recommendations for sponsors of medically important antimicrobial drugs approved for use in animals to voluntarily bring under veterinary oversight all products that continue to be available overthe-counter. (GFI #263). Food and Drug Administration. *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-263-recommendations-sponsors-medically-important-antimicrobial-drugs-approved-use-animals*

Best Practices for Parasite Management

Develop an effective parasite control program, which may include programs like refugia (worms still susceptible to dewormers) with the herd veterinarian or parasite specialist and use diagnostic testing, such as Fecal Egg Count Reduction Tests (FECRT), as part of a parasite control program. Targeted selective treatment and non-treatment strategies can be discussed. In some cases, not all animals will need dewormed. Fecal testing may help decide if the herd needs dewormed or not.

Have accurate weights so animals are not underdosed, which can lead to parasites like worms or flies that are not completely killed, and gives resistant parasites a higher chance of surviving. Average purchase weights of groups are not sufficient because this leads to some of the group being underdosed.

Proper application of all antiparasitic products is crucial to their function.

- Topical pour-on products must be applied from the withers to the tailhead.
- Oral drenches must be administered over the lump of the tongue to ensure product is swallowed.
- Administer injectables following all BQA principles.
- In-feed/mineral use must be fed and used per label directions.
- Only use antiparasitic products for parasites and dosage listed on the label (do not use dewormer for fly control).

Consider using Integrated Pest Management strategies to reduce risks from pests like insects, parasites, and others. These diverse control strategies may include pasture rotation, fly traps, breeding animals for resistance, judicious use of veterinary medications, and others.

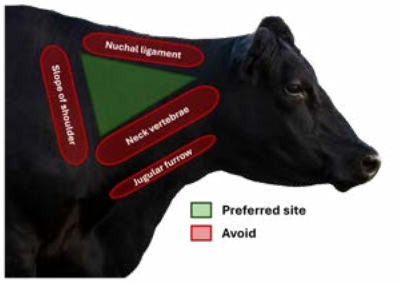
STEPS TO PREVENT A VIOLATIVE RESIDUE

When following BQA guidelines, the risk of residue violations is lowered. For detailed guidelines and background, the BQA National Manual and Field Guide are available for download at *www.bqa.org*. Some recommendations for on farm practices include:

- Always read label and dosing instructions on all animal health products prior to herd health procedures.
- Maintain the cold chain during delivery, transportation, and storage of vaccines and other refrigerated products, which should be stored in a dependable refrigeration unit that maintains a temperature as directed by the product label (typically 35-45°F).
- Protect animal health products from extreme temperatures and sunlight exposure which could limit effectiveness, inactivate, or cause toxicity. Do not use vaccines if they are accidentally frozen.
- It is recommended to store different classes of products (e.g., vaccines, dewormers, antibiotics, others) on separate shelves to minimize the risk of choosing the wrong product. Label shelves to better organize and find products.
- Expired products should not be used because they have lost efficacy, could cause adverse reactions, and are considered adulterated by the FDA. Properly discard or return out-of-date products according to the state or local medical waste disposal guidelines.
- Regardless of animal's age, injections should be given in front of the shoulder slope (unless directed otherwise by a veterinarian or per label instruction). To avoid adverse tissue reactions, inject products in the neck subcutaneous (SQ) whenever possible, or choose products that can be given intravenous (IV), intranasal (IN), or orally.
- Space injections at least 4 inches apart (about a hand's width). This reduces the risk of the products mixing together which could cause a reaction or inactivate the products. If giving multiple injections, the highest volume should be given in the bottom of the injection triangle, so product drainage does not interfere with other injections. Use both sides of the neck if accessible.
- Cattle identification contributes to quality record keeping and has many management and production benefits.

The Injection Triangle

- Upper border is below nuchal ligament (2" below topline)
- Lower border is above neck vertebrae
- In front of the slope of the shoulder



- Realize that compromised animals may have extended withdrawal times. Work with your veterinarian on appropriate withdrawal times.
- Keep records of all products administered including date, animal identification, product used, serial number, amount administered, route of administration, person administering, and withdrawal time.
- Properly restraining animals assures good neck access and proper injection technique, minimizes risk of needles breaking or bending, and minimizes risk of human or animal injury.
- If intramuscular medications must be used, administer them in the neck and never exceed 10 cc per IM injection site. For example, if 24 cc is the calculated dose, use three 8 cc IM injections instead of two 12 cc IM injections.
- Limit the volume of SQ injections as indicated by the product label or as instructed by the herd veterinarian. If the label does not specify the maximum volume per injection site, the maximum volume per injection site should be limited to 10 cc.
  - Exceeding these volumes can lead to reduced efficacy and drug absorption, tissue damage, and risk for violative residues.

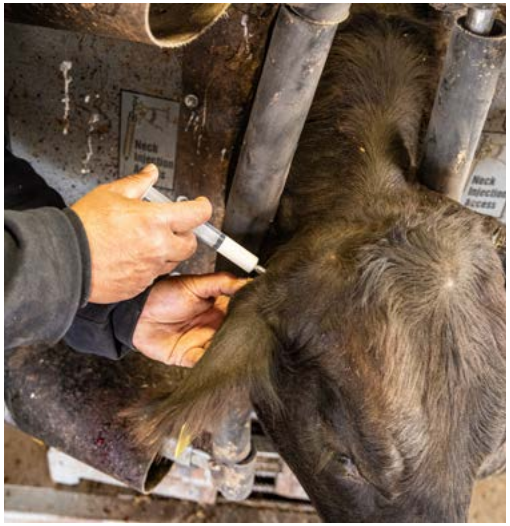
BQA Needle Size Recommendations for Cattle Injections

Injectable Viscosity	Route of Administration								
	Subcutaneous (SQ) (½ to ¾ inch needles)			Intramuscular (IM) (¾ to 1 inch needles)			Intravenous (IV) (1 to 1 ½ inch needles)		
	Cattle Weight (lbs)			Cattle Weight (lbs)			Cattle Weight (lbs)		
	< 300	300-700	> 700	< 300	300-700	> 700	< 300	300-700	> 700
Thin Example: Most Vaccines	18 gauge	18 - 16 gauge	16 gauge	20 - 18 gauge	18 - 16 gauge	18 - 16 gauge	18 - 16 gauge	18 -16 gauge	16 - 14 gauge
Thick Example: Thick Antibiotics	18 - 14 gauge	18 - 14 gauge	16 - 14 gauge	18 - 16 gauge	18 - 16 gauge	16 gauge	18 - 16 gauge	18 - 16 gauge	16 - 14 gauge
SELECT THE NEEDLE TO FIT THE CATTLE SIZE (USE THE SMALLEST PRACTICAL SIZE WITHOUT FEAR OF BENDING)									

Needle Selection and Product Administration Tips

- Confirm with the herd veterinarian on needle size recommendations for the operation.
- Select a short needle (1/2" to 3/4") for SQ injections. Recommend 1/2" needles for cattle less than 400 lbs, 5/8" needles for older cattle, and 3/4" for thick-hided animals.
- IM injections require at least a 3/4" needle to get into the muscle. Thick-hided animals may require 1" or longer needles.
- The smaller 18 gauge needles are good for cattle less than 400 lbs, while 16 gauge needles work for cattle larger than 400 lbs.
- Extremely thick (viscous) products require a needle with a gauge larger than 16 gauge (such as 14 gauge x 5/8" and 14 gauge x 3/4").

- Change needles
  - Immediately if the needle is bent, burred, or dirty with feces, blood, dirt, or irritating chemicals.
  - DO NOT STRAIGHTEN OR USE A BENT NEEDLE.
  - Between cattle with KNOWN bloodborne infectious disease. Talk to your veterinarian about reducing the risk of pathogen spread through needles for diseases such as anaplasmosis or bovine leukemia.
  - Every 10 to 15 injections for disposable needles (at a minimum).
  - Under the instruction of the herd veterinarian.
- Needle Care
  - Protect needles from contamination with feces, dirt, or irritating chemicals.
  - Use case or holder to protect syringes and needles during processing such as a vaccine cooler with syringe holder.
  - Protect cattle handlers from accidental needle sticks by being aware of surroundings and understanding the risks of the vaccines or products being used.
  - Store unused needles in area protected from moisture, temperature and contaminants.



- Needle Disposal
  - Needle sticks can be a human safety risk, especially if the vaccine or product is hazardous to human health.
  - Place in a puncture-proof container with a secure lid.
  - Follow local, state, and federal EPA guidelines for disposal of used needles and other sharps.
  - Work with the herd veterinarian for proper sharps disposal recommendations.
- Disinfectants
  - DO NOT use disinfectants on needles used for fluid injectables, especially MLV.
  - Replace needles rather than disinfect.
  - Recommended for cleaning implanting gun needle between animals.

Concerns With Using Remote Drug Delivery (RDD) Systems When Administering Animal Health Products

RDD systems are used to administer medication to or chemically restrain animals that cannot be caught or there is a human safety concern with their handling. Dart guns are a common type of RDD used in the cattle industry.

RDD technology creates issues with the proper administration of animal health products and appropriate injection methods, depending on charge of device, distance to animal, environmental components, and skill of the person.

Darts delivered with an RDD can inadvertently strike sensitive tissues, such as the nose or eye; deliver the product into a non-BQA compliant area (i.e., round, loin, shoulder) rather than the injection triangle of the neck; or administer the product IM rather than SQ or vice versa.

Research has repeatedly demonstrated failure of RDD systems to consistently deliver the intended labeled dose of the antibiotics commonly used to treat bovine respiratory disease in beef cattle tested.[10,11,12] Underdosing or not injecting the full amount leads to failure to achieve the FDA approved levels of the antibiotic. This contributes to treatment failure and potential antimicrobial resistance due to underdosing.

Entire darts or dart components embedded in the muscle tissue from cattle have and continue to be found during fabrication of carcasses in packing plants. Foreign objects in beef are an important food safety and consumer confidence issue with animal welfare and sustainability concerns. All of these are considered adulterants by the USDA FSIS and by the FDA.[13] Products containing foreign object contamination cannot be sold for human consumption and entire animals can be condemned at the plant.

It is recommended that anyone utilizing RDD technology complete an appropriate firearm or RDD safety training course and seek guidance and training on the specific device being used from the device manufacturer. In situations in which remote delivery of medication must be used, it should comply with BQA guidelines for injection site selection (in the injection triangle of the neck), routes of administration (SQ preferred), and needle selection. Treated animals should have clear identification and treatment and animal health records to avoid residue violations and foreign object contamination.

While BQA recognizes RDD use in emergency situations when chemical restraint is necessary for human or animal safety, BQA does not support the routine use of RDD for treatment purposes.

10. Coetzee *et al.* 2018. Pneumatic dart delivery of tulathromycin in calves results in lower antimicrobial concentrations and increased biomarkers of stress and injection site inflammation compared with subcutaneous injection. J. Anim. Sci. 96:3089-3101. *https://doi.org/10.1093/jas/sky222*
11. Rivera *et al*. 2019. Pharmacokinetics of tulathromycin following administration to stocker cattle with remote delivery devices. J. Anim. Sci. 97:4482-4487. *https://doi.org/10.1093/jas/skz311*
12. Hairgrove *et al*. 2021. Effects of delivery via pressure-adjustable pneumatic gas-powered dart gun of three antimicrobial drugs (ceftiofur crystalline free acid, tildopirosin, and tulathromycin) on drug disposition and meat quality in cattle. *https://peerj.com/articles/11822/*
13. Adulterated Food, 21 C.F.R. § 342 (2025). *https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section342&num=0&edition=prelim*

RECORDKEEPING IS ESSENTIAL TO DOCUMENT THERAPY AND MONITOR WITHDRAWAL TIMES

Record keeping is a key element of Beef Quality Assurance and a good business practice in general. A quality record keeping system is one that cattle producers are comfortable using and that maintains accurate, thorough, and timely production records. There are many software programs designed for cattle production. If organized well, using pen and paper is a feasible option that is better than not having a record keeping system. Maintaining accurate records helps with the management of herd health, biosecurity, worker training, nutrition programs, and overall production costs.

- The important thing is to find a method that you are comfortable with, which allows you to maintain accurate, thorough and timely documentation of your herd health program, nutrition program and other important production factors.
- For example, animal health records tell the manager and veterinarian what treatments are being used so they can make sure that recommendations are being followed and help them decide whether treatment protocols need to be adjusted.
- To inspire consumer confidence we must be able to document the responsible use of products and demonstrate that we have control over risk factors that have residue potential. Good records are also important if your operation is inspected (for example, if one of your market cows is found to have a violative residue) by any state or federal agency.
- Should your operation get cited for a residue violation and you believe it's a case of mistaken identity, good records are your only evidence that the animal in question does not belong to you. Or, if it is your animal, then your records may help prove the animal was not given the particular drug in question by you.
- Effective documentation showing appropriate training, inventory control, product use, animal identification, withdrawal and disposal is the only way to avoid liability from a residue contamination. The only way to accurately determine if you are in compliance with withdrawal times is to know exactly what was given, how much was given, where it was given, how it was given and when it was given to the animal.
- Updated records also allow you to make well-informed decisions about marketing cattle without worrying whether enough time has elapsed since the last treatment or therapy. Records should also be kept on your use of pesticides, herbicides and other chemicals. Records will also help in the case of an adverse reaction or residue investigation.
- Understand the remarks and safety restrictions with regard to withdrawal times and animal types (pregnant, lactating, etc.) that should not be treated or exposed to treated areas.

What to include in a record

Keep all records for at least two years from the date of transfer or sale of the cattle. In case a problem arises later, your records will help you track the treatment and therapy history of the animal when it was in your possession.

The animal health record should contain the following information:

- Treatment date or therapy
- Animal or group identification
- Approximate weight of animal or group average
- Product administered
- Product lot/serial number
- Earliest date the animal could clear withdrawal time
- Dose given
- Route of administration (IM, SQ, etc.)
- Location of injections
- Name of person who administered the drug

A copy of the appropriate records should be made available to the buyer of your cattle or as they are transferred from one unit of your ranch to another. Records should include all individual and group treatment or therapy processing history and other information as deemed appropriate.

The BQA program recommends keeping records for a minimum of two years, or longer as required by laws/regulations. Pesticide records should be kept for three years. Veterinary Feed Directive records should be kept for two years.

- Having all product withdrawal times listed in a treatment or animal health protocol book is a best management practice.
- Proper record keeping, storage, and handling of animal health products are important to ensure efficacy of the products and are key to a cattle health program.
- Record product information including the receiving date, name, quantity, unit sizes, lot/serial numbers, and expiration dates in receiving and inventory records. This could be important if a product is recalled, or cattle have an adverse reaction.
- Where applicable, keep complete records when formulating or feeding medicated feed rations. Feed additive and feed additive records are to be kept a minimum of two years, or longer as required by laws/regulations.
- All VFD records must be kept and be available for inspection for two years by the issuing VCPR veterinarian, the cattle producer, and the feed mill distributing the VFD medication. Producers must follow the veterinarian's instructions for all drug use, including ELDU, including following extended withdrawal times, maintaining records, and identifying treated animals.

EMPLOYEE TRAINING AND SAFETY

It is the responsibility of each operation to cultivate a culture of safety and to provide training and support to everyone in the facility, from managers to feeders to family members, including children. Incorporating worker safety training on a monthly, semi-annual, or annual basis can include many aspects of cattle care such as how to improve human interaction with animals and equipment in a safe work environment.

To ensure safe environments, employee training in topic areas for the entire team should be emphasized and developed. Clear communication and training is key to human and animal safety.

Cattle producers and employees have the responsibility to understand what products they are using, why the products are needed, and how to properly handle them to optimize effectiveness. Properly restraining animals assures good neck access and proper injection technique, improves human safety, minimizes risk of needles breaking or bending, and minimizes animal injury. Employees administering animal health products should be properly trained according to BQA guidelines and proper protocols.

Safety or role-specific training should be held at least annually for all cattle caretakers. Trainings should be provided in a language that the employee understands and in a way they understand (such as written, oral, video, or other). For employee training and worker safety resources, visit *www.bqa.org*.

View and download the BQA National Manual, Field Guide, and other resources.

Example Vetrinarian-Client-Patient Relationship (VCPR) Agreement

A valid VCPR requires:

- Consent from the farm owner/ producer to enter the VCPR.
- The veterinarian has enough knowledge of the farm and animals to make a preliminary diagnosis.
- The veterinarian assumes responsibility for medical decisions and treatment needs.
- Farm owner/producer and workers agree to follow the veterinarian's instructions.
- The veterinarian is available for follow-up and sets a schedule for timely visits.
- *If drugs are used against the veterinarian's instructions, the VCPR is violated and becomes void.*

Farm Information

Owner/Producer Name: _____ Date: _____

Mailing Address: _____

City: _____ State: _____

Farm Name: _____

Farm Address (if different from above): _____

Premises ID Number (Optional):_____

Email: _____ Phone Number:_____

Veterinarian Information

Name: _____

Clinic Name: _____

Mailing Address: _____

City: _____ State: _____

Phone: _____ Email: _____

State(s) Licensed In: _____

Other: _____

I hereby certify that a valid Veterinarian-Client-Patient Relationship (VCPR) is established for the above listed farm and veterinarian and will remain in force until canceled by either party, or 1 year from the signature date below.

Producer Signature: _____ Date: _____

Veterinarian of Record Signature: _____ Date: _____

Scan to view BQA VCPR form.

For more information visit:
www.bqa.org

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