

American Association of Swine Veterinarians Basic Guidelines of Judicious Therapeutic Use of Antimicrobials in Pork Production

(Approved by the AASV – October 2014)

Veterinarians agree to protect animal and public health when they pledge the Veterinarian's Oath. This oath is as applicable today as it was when it was written many years ago. Swine veterinarians are committed to "the use of scientific knowledge and skills for the benefit of society." This commitment remains the core of swine veterinarian efforts to achieve "the protection of animal health and welfare, the prevention and relief of animal suffering, the conservation of animal resources, the promotion of public health, and the advancement of medical knowledge."

Position Statement

When a condition exists that threatens or impairs pig health and wellbeing, it is essential that an accurate clinical diagnosis be obtained. Appropriate diagnostic techniques and clinical experience should substantiate a presumptive diagnosis. Once the decision is reached to use antimicrobials for therapy, swine veterinarians strive to optimize therapeutic efficacy, minimize resistance to antimicrobials, and protect public and pig health.

The American Association of Swine Veterinarians supports and is committed to the following objectives as developed by the American Veterinary Medical Association's Steering Committee on Judicious Therapeutic Antimicrobial Use:

- Support development of a scientific knowledge that provides the basis for judicious therapeutic antimicrobials use.
- Support educational efforts that promote judicious therapeutic antimicrobials use.
- Preserve therapeutic efficacy of antimicrobials.
- Ensure current and future availability of veterinary antimicrobials.

Judicious Therapeutic Use of Antimicrobials Principles for Swine Veterinarians

- Implement preventive strategies, such as appropriate husbandry and hygiene, routine health monitoring, and immunization to optimize pig health.
- Recognize that in spite of best efforts towards preventive strategies, there are times when swine veterinarians need to prescribe treatment for individual and herd conditions. This is a part of the veterinarians' oath to "protect animal health and welfare." Use the following suggested steps to assess necessity for judicious therapeutic use of antimicrobials.
 - Evaluate and quantify the severity and prevalence of clinical signs.

- Via clinical assessment and diagnostics, establish the differential diagnosis list; and if possible, the definitive diagnosis.
- Recognize, investigate, and address the roles played by the following factors in the course of the disease(s):
 - Genetics
 - Genetic sources
 - Genetic predisposition
 - Nutrition
 - Water availability and quality
 - Protein
 - Energy
 - Micronutrients
 - Housing
 - Air space per pig
 - Temperature extremes beyond the thermal comfort zone of swine
 - Meteorological conditions (e.g., seasonal patterns)
 - Ventilation
 - Management
 - Stocking density
 - Appropriate biosecurity controls of animals and humans
 - Isolation and acclimatization of incoming breeding swine
 - Appropriate and timely use of cleaning, disinfection and drying of premises
 - Depopulation/repopulation to eliminate a disease organism
 - Stockperson ability and training
 - Health

- Immune status of the animals
 - Herd dynamics and health status of the sow herd
 - Presence and importance of concurrent infections
 - Source of pigs (e.g., single source or multiple sources)
 - Other preventative strategies
- Consider other therapeutic options prior to, or in conjunction with, antimicrobial therapy.
 - Examples include acidification of feed or water, electrolyte therapy, supportive care (e.g., antipyretic therapy).
- Meet all requirements of a veterinarian-client-patient relationship (VCPR).
 - Judicious antimicrobial use requires the oversight of a veterinarian at some point in the decision making process. (See glossary for definition of VCPR).
- Prescribe extra-label antimicrobial therapy only in accordance with the Animal Medicinal Drug Use Clarification Act amendments to the Food, Drug, and Cosmetic Act and its regulations.
 - Understand and review the list of drugs prohibited for extra-label use in food animals (Appendix A). This list is subject to change. For the current list, see the [Code of Federal Regulations, Section 530.41 - Drugs prohibited for extralabel use in animals](#) [Drugs prohibited for extralabel use in animals](#).
 - For more information on extra-label drug use, see [The Ins and Outs of ExtraLabel Drug Use in Animals: A Resource for Veterinarians](#), published by the FDA.
 - Remember that the law prohibits extra-label use of any antimicrobials in feed.
- Work with those responsible for the care of pigs to use antimicrobials judiciously regardless of distribution system through which the antimicrobial was obtained.
 - Judicious use requires the oversight of a veterinarian at some point in the decision making process.
 - Veterinarians must accurately communicate written, adequate directions to the client for antimicrobial use.
 - Veterinarians are the primary source of information and training on the use of swine antimicrobials.
 - The Pork Quality Assurance® Plus (PQA Plus®) program of the National Pork Board provides a basis for the judicious use of antimicrobials.

- The AASV recognizes the legal availability of antimicrobials obtained through over-the-counter (OTC) distribution channels.
- The extra-label uses of OTC antimicrobials fall within the regulatory constraints of the Animal Medicinal Drug Use Clarification Act and thus requires the oversight of a veterinarian.
- Optimize regimens for antimicrobial therapy using current pharmacological information and principles.
 - Package inserts should be considered as sources of information for the practitioner.
 - Veterinarians should adhere to the additional constraints associated with the appropriate use of restricted-use antimicrobials, e.g. enrofloxacin and ceftiofur
 - Enrofloxacin is prohibited from extra-label uses in all food-producing animals.
 - Ceftiofur has restricted extra-label uses. It is prohibited from extra-label use for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; or if the drug is not approved for that species and production class.
 - Continuing education is an important component of maintaining and enhancing the veterinarian's pharmacological knowledge. Combinations that do not currently have FDA approval should not be used in the absence of supporting scientific pharmacological data.
 - The compounding of antimicrobials should be avoided in those instances where there is a lack of supporting scientific pharmacological data.
 - For more information on compounding, see the FDA Compliance Policy Guide entitled [*Compounding of Drugs for Use in Animals*](#).
 - Cost is not a factor when considering the appropriate use of antimicrobials.
- Use antimicrobials following careful review.
- Follow label directions or, when extra-label use is clinically necessary, follow AMDUCA regulations ([*Extralabel drug use algorithm*](#)).
 - Therapeutic exposure involves both dose and duration.
 - Continued use of antimicrobials in chronic, non-responsive clinical cases should be discouraged.

- Withdrawal times must always be considered during the selection of antimicrobials.
- Use historical outcomes and clinical experience in the selection of antimicrobials.
- Use adequate laboratory support for antimicrobial decision making.
 - Utilize culture and susceptibility results to aid in the selection of antimicrobials.
 - Veterinarians should utilize appropriate references for proper procedures and accurate interpretation of susceptibility results, such as the NCCLS publication, [*Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Approved Standard.*](#)
 - An accurate diagnosis includes characterization of etiology.
- Devise a plan for treatment of ill or at-risk animals.
 - Consider group morbidity and mortality rates and herd health history when deciding whether or not to initiate herd, group, or individual therapy.
 - When these factors are appropriately considered, preventative therapy may be a judicious use of antimicrobials.
- Minimize environmental contamination with antimicrobials..
 - Properly adjust water medicators and feeders.
- Record all antimicrobial treatments.
 - AASV recommends the use of treatment records such as those proposed by the [Pork Quality Assurance® Plus \(PQA Plus®\) program](#) of the National Pork Board.
 - Good treatment records combined with accurate animal or group identification are necessary to adhere to prescribed withdrawal times for effective residue avoidance.
- Periodically reevaluate antimicrobial use.
 - Regularly monitor compliance.
 - Regularly review records.
 - Regularly assess outcomes.

Glossary:

Antibiotic --a chemical substance produced by a microorganism which has the capacity, in dilute solutions, to inhibit the growth of or to kill other microorganisms.

Antimicrobial --an agent that kills bacteria or suppresses their multiplication or growth. This includes antibiotics and synthetic agents. This excludes ionophores and arsenicals.

Narrow Spectrum Antimicrobial --an antimicrobial effective against a limited number of bacterial genera; often applied to an antimicrobial active against either Gram-positive or Gram-negative bacteria.

Broad Spectrum Antimicrobial --an antimicrobial effective against a large number of bacterial genera; generally describes antibiotics effective against both Gram-positive and Gram-negative bacteria.

Antibiotic Resistance --a property of bacteria that confers the capacity to inactivate or exclude antibiotics or a mechanism that blocks the inhibitory or killing effects of antibiotics.

Extralabel -- use means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.

Immunization --the process of rendering a subject immune or of becoming immune, either by conventional vaccination or exposure.

Monitoring --monitoring includes periodic health surveillance of the population or individual animal examination.

Therapeutic --treatment, control, and prevention of bacterial disease.

Veterinarian/Client/Patient Relationship (VCPR) --

When using a drug extra-label, refer to the VCPR as it appears in 21 CFR Part 530, "Extra-label Drug Use in Animals":

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=530.3>

When using a drug according to the label direction, refer to your state's specific VCPR definition:

https://www.avma.org/Advocacy/StateAndLocal/Documents/vcpr_and_prescriptions.pdf

Veterinary Feed Directive (VFD) Drug --The VFD category of medicated feeds was created by the Animal Drug Availability Act of 1996 to provide an alternative to prescription status for certain therapeutic animal pharmaceuticals for use in feed. Any animal feed bearing or containing a VFD drug shall be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian in the course of the veterinarian's professional practice.

Appendix A:

Code of Federal Regulations

Title 21 - Food and Drugs Volume: 6

Date: 2013-04-01

Original Date: 2013-04-01

Title: Section 530.41 - Drugs prohibited for extralabel use in animals.

Context: Title 21 - Food and Drugs. CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED). SUBCHAPTER E - ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS. PART 530 - EXTRALABEL DRUG USE IN ANIMALS. Subpart E - Safe Levels for Extralabel Use of Drugs in Animals and Drugs Prohibited From Extralabel Use in Animals. § 530.41 Drugs prohibited for extralabel use in animals.

(a) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in food-producing animals.

(1) Chloramphenicol;

(2) Clenbuterol;

(3) Diethylstilbestrol (DES);

(4) Dimetridazole;

(5) Ipronidazole;

(6) Other nitroimidazoles;

(7) Furazolidone.

(8) Nitrofurazone.

(9) Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine);

(10) Fluoroquinolones; and

(11) Glycopeptides.

(12) Phenylbutazone in female dairy cattle 20 months of age or older.

(13) Cephalosporins (not including cephalirin) in cattle, swine, chickens, or turkeys:

(i) For disease prevention purposes;

(ii) At unapproved doses, frequencies, durations, or routes of administration; or

(iii) If the drug is not approved for that species and production class.

(b) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in nonfood-producing animals: [Reserved]

(c) [Reserved]

(d) The following drugs, or classes of drugs, that are approved for treating or preventing influenza A, are prohibited from extralabel use in chickens, turkeys, and ducks:

(1) Adamantanes.

(2) Neuraminidase inhibitors.

[62 FR 27947, May 22, 1997, as amended at 67 FR 5471, Feb. 6, 2002; 68 FR 9530, Feb. 28, 2003; 68 FR 14134, Mar. 24, 2003; 71 FR 14377, Mar. 22, 2006; 77 FR 745, Jan. 6, 2012]