

Antibiotic Use and Managing Resistance | fact sheet



Antibiotics, sometimes called antimicrobials, made specifically for cattle are used to help prevent, control or treat illnesses. Cattlemen consult with veterinarians to develop health programs for their cattle designed to keep cattle healthy and protect the future use of antibiotics for human and animal health. This process assures animals remain healthy and the food supply remains safe.

Judicious Use of Antibiotics

Since the 1980s, the Beef Quality Assurance program has set standards and helped train farmers and ranchers about the appropriate use of antibiotics on farms and ranches.¹

- The guidelines are based on the American Veterinary Medical Association (AVMA), the American Association of Bovine Practitioners (AABP) and the Academy of Veterinary Consultant's (AVC) judicious use guidelines.
- The Producer Guidelines for the "Judicious Use of Antimicrobials," has been in place since 1987 and outlines the following:¹
 - o Avoid using antibiotics that are important to human medicine
 - o Avoid the selection of an antibiotic with a broad spectrum of activity, whenever possible.
 - o Limit antibiotic use to sick or at risk animals.
 - o Antibiotics should be –used to prevent, treat or control disease and should not be used if the primary intent is to improve performance.
- The beef community discourages feeding low levels of antibiotics to promote growth, because of concern over resistance.

Antibiotic Resistance

- The U.S. government strictly tracks antibiotic resistance, monitors and reviews products and interventions.²
 - o In 2003, the Food and Drug Administration (FDA) implemented Guidance 152, which adds additional safety measures to prevent antimicrobial resistance that may result from the use of antimicrobial drugs in animals.³
- By law, no meat sold in the United States is allowed to contain antibiotic residue that violate FDA standards. USDA's Food Safety & Inspection Service through the National Residue Program conducts tests to ensure beef products entering the food supply do not contain antibiotic levels that violate FDA standards. This testing protocol has been updated continuously since its inception in 1967.⁴
- According to a comprehensive scientific summary published by the Institute of Food Technologists (IFT), the use of antibiotics has been "remarkably successful in providing safe foods and has not been compromised by occurrence of resistant microorganisms."⁵
- The beef industry has funded more than 13 comprehensive research studies to enhance the understanding of the basic science of resistance development, as well as connect information on the effects of beef production practices on resistance development on food borne pathogens.⁶

1 National Beef Quality Assurance Manual <http://www.bqa.org/CMDocs/bqa/NationalManual.pdf>

2 National Antimicrobial Resistance Monitoring System, <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm059103.htm>

3 Food and Drug Administration: Guidance for Industry, <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf>

4 USDA FSIS Blue Book http://www.fsis.usda.gov/Science/2012_Blue_Book/index.asp

5 Institute of Food Technologists "Dealing with Antimicrobial Resistance" Summary, 2006. http://www.ift.org/Knowledge-Center/Read-IFT-Publications/Science-Reports/Expert-Reports/Antimicrobial-Resistance/~/_media/Knowledge%20Center/Science%20Reports/Expert%20Reports/Antimicrobial%20Resistance/foodtech_0806antimicrobial.pdf

6 Beef Research www.beefresearch.org

Antibiotic Approval Process

All antibiotics labeled for use in livestock production have passed a stringent FDA approval process and have been shown to be safe and effective.

The Center for Veterinary Medicine (CVM), a branch of the Food and Drug Administration (FDA), ensures that animal drugs are safe, effective, and manufactured to the highest quality standards under the guidance of the Federal Food, Drug and Cosmetic Act.

For any new food animal antibiotic to be approved, a New Animal Drug Application (NADA) must be initiated, typically by the drug manufacturer.

The NADA process includes three components:

Safety assessment

The sponsor must submit an average of 75 different studies to prove an antibiotic's safety in three areas.

Human food safety: NADA sponsors must provide empirical evidence that food derived from treated animals is safe for human consumption.

Reviews also include a comprehensive, evidence-based approach to address antibiotic resistance.

Target animal safety: Research must confirm the antibiotic is safe for the animals that will be treated.

Environmental safety: A drug manufacturer must measure and prove that a proposed product and its metabolized byproducts do not harm the environment in any way.

Efficacy assessment

Data must show the product will work in the ways intended, which include controlling and treating clinical disease.

Quality assessment

Consists of:

- Facility inspections
- Assurance of product stability
- Adherence to Good Manufacturing Practices and other procedures to assure FDA the NADA sponsor can manufacture the product in

Ongoing monitoring

Includes residue monitoring at meat harvest facilities by the Food Safety Inspection Service (FSIS). The U.S. Department of Agriculture (USDA), FDA and the Centers for Disease Control and Prevention (CDC) collaborate to collect data through the National Antimicrobial Resistance Monitoring System (NARMS). Manufacturers are required to annually submit a report to FDA detailing the drug's active ingredients, distribution, proposed usage and any new scientific data related to product safety.

Additional safeguards

All animal medicines, including antibiotics, are subject to ongoing evaluation through science-based risk assessments after they have been approved by FDA.

Antibiotics are required to go through a comprehensive, multi-step scientific review by FDA to ensure animal health and human food safety. Approved products must be continually proven safe to remain on the market.