



Antibiotics on the Farm: What You Need to Know about New Regulations

Overview

On Jan. 1, 2017, the U.S. Food and Drug Administration's (FDA) new regulations addressing on-farm antibiotic use in food-animal production will take effect. The agency's effort is aimed at eliminating the use of medically important (to human illness) antibiotics for growth promotion purposes in food-animal production and bringing therapeutic use in feed and water – to treat, control or prevent specific disease – under additional veterinary oversight. Producers, veterinarians, feed mills and suppliers, will all face new requirements.

FDA's New Regulations Defined

All sectors of animal agriculture, from drug companies to producers and veterinarians to feed mills, are collaborating to implement the new FDA antibiotic regulations:

Guidance 209: In 2010, FDA outlined its intent and recommendations regarding growth promotion uses of medically important antibiotics in food animal production. FDA also specified that veterinarian oversight will increase for the remaining therapeutic applications (prevention, treatment and control) of medically important antibiotics. This action applies to both feed-grade and water-based antibiotics.

Guidance 213: On Dec. 11, 2013, FDA initiated a three-year transition process to complete its food-animal antibiotic strategy. This action requests animal-health companies to outline intentions to voluntarily remove any production/growth-promotion uses from product labels of medically important antibiotics. The guidance also eliminates over-the-counter status of these medications and increases veterinary oversight for on-farm therapeutic use by requiring a veterinary feed directive (VFD) for feed applications and a prescription for water treatments. Jan. 1, 2017, is when implementation must be completed.

Final VFD Rule: On June 3, 2015, FDA announced the final VFD rule. The final rule outlines specific requirements of the VFD process for medically important (to treat human infections) feed-grade antibiotics.

Basics of On-Farm VFD Compliance for Producers

The biggest change for pork producers, veterinarians and feed mills will be the expanded Veterinary Feed Directive (VFD) process. Previously, only three products required a VFD, and all are labeled for swine use. While the current VFD regulation may offer some familiarity with the compliance process, the new FDA rule will require some additional time and effort on the part of producers and their veterinarians. Here are some key steps required to comply:

- The issuing veterinarian is required to keep the original VFD; the feed mill/distributor and producer (client) must each keep a copy of the VFD. Hardcopy or electronic versions are allowed.
- The VFD and records of the related feed distribution must be kept for a period of two years.
- Each VFD includes a specific expiration date. Any VFD feed remaining after its related VFD has expired may not be fed to animals without obtaining a new VFD. This would include any remaining feed in a bin or feeder.

The take-home message for producers: Talk with your veterinarian about using any antibiotics that fall under the new VFD requirement. Most antibiotics labeled for use in swine will be affected by the VFD rule; however, a few compounds of interest will not be affected. These include bacitracin, tiamulin, carbadox, ionophores and bambarmycin. For a list of affected products, go to www.pork.org/antibiotics.

Veterinary-Client-Patient Relationship Required

The new FDA antibiotics regulations will require pig farmers to have a valid veterinary-client-patient relationship (VCPR). Depending on the state in which the veterinarian practices, he or she can only issue a VFD in the context of a valid VCPR as defined by the state requirements. In simplest terms, this means a pig farmer will need to have a good relationship with their veterinarian and expect to spend more time in developing a plan that satisfies all VFD requirements. As for the veterinarian's role, he or she must be familiar with the production practices and herd health profile.

In states that do not have VCPR requirements applicable to VFDs, the veterinarian will be required to follow the federal VCPR standards, which are outlined in the FDA regulation. The agency has posted a list of states on its website that do and do not have VCPR requirements for VFDs, as well as the key elements of the federally-defined VCPR. The list may change over time as states update their veterinary practice requirements. To determine if your state or federal definition of a VCPR prevails, go to the FDA tab at www.pork.org/antibiotics.

Record-keeping Priorities

Producers, veterinarians and feed processors will all need to be especially diligent in keeping records associated with VFDs and prescription water antibiotics once FDA's new policies go into effect. Producers with Pork Quality Assurance® Plus (PQA Plus®) certification should be well familiar with requirements for accurate and complete record-keeping.

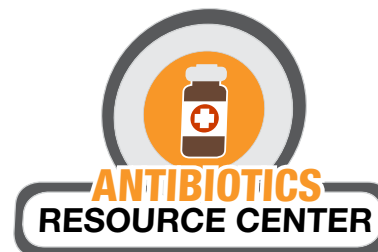
The "Pen or Individual Pig Treatment Record" within PQA Plus provides guidance on the type of records that FDA will require. The number of animals, reason for treatment, product name and who administered the treatment, are among the data to be recorded.

The record-keeping commitment will involve keeping hard copies or electronic versions of all VFDs for two years and one year for all prescriptions. The issuing veterinarian will maintain the originals for the same timeline. Distributors who manufacture VFD feed also will keep VFD copies for two years. Any of the parties must be able to provide the VFD orders (and prescriptions) to FDA upon request.

USCARE: Your Checklist for Antibiotic Success

The Pork Checkoff offers USCARE as an easy way to remember the six key steps producers need to complete before January 2017 to ensure successful compliance with FDA's new regulations for on-farm use of medically important (to human health) antibiotics.

- **U**nderstand the new feed (Veterinary Feed Directive) and water (prescription) rules: As of Jan. 1, 2017, growth promotion use of medically important (to human health) antibiotics will not be allowed. Only therapeutic use (treatment, control, prevention) for a specific animal health condition will be allowed under the direction of a veterinarian.
- **S**trengthen your veterinary-client-patient relationship (VCPR): Schedule periodic herd visits with your veterinarian and review health monitoring and herd health strategies.
- **C**ommunicate with your feed mill: Ensure the mill personnel understand and are prepared to implement new VFD record-keeping procedures for antibiotics and that stringent feed delivery protocols are in place.
- **A**ssess your herd health and welfare strategies: Sit down with your veterinarian to outline production and management changes to maximize animal health and minimize antibiotic use.
- **R**enew your commitment to responsible antibiotic use: Stay up to date with Pork Quality Assurance Plus certification and make it part of your worker education program.
- **E**nsure your record-keeping compliance: For producers, this means keeping copies (print or electronic) of VFD for two years and prescription records for one year.



www.pork.org/antibiotics

PQA Plus Provides Antibiotic Guidance

The Pork Quality Assurance® Plus (PQA Plus®) on-farm education and certification program outlines Good Production Practices to help guide pork producers and their employees in the responsible use of antibiotics on the farm. Here's a look at the Five Principles:

- **Principle 1:** Take appropriate steps to decrease the need for the application of antibiotics.
- **Principle 2:** Assess the advantages and disadvantages of all antibiotic use.
- **Principle 3:** Use antibiotics only when they will provide measurable benefits.
- **Principle 4:** Fully implement management practices for responsible use of animal-health products into daily operations.
- **Principle 5:** Maintain a working veterinary/client/patient relationship.

PQA Plus also provides useful tools that can be applied on the farm to help in the regulatory transition, such as:

- Drug storage inventory sheet
- Medicated feed-mixing record
- Pen/individual treatment record

Note: A new version of PQA Plus will be launched in June during the 2016 World Pork Expo, including a section on responsible antibiotic use. For more information about PQA Plus, go to www.pork.org/certification.

Expanding the Herd Health Role

Responsible use of antibiotics is just one part of an overall herd health management plan. Producers should sit down with their veterinarians to discuss how to apply the new VFD and prescription requirements and other herd health strategies. A veterinarian can help design herd health and production plans to decrease disease, enhance performance and produce safe, wholesome pork. Each producer should review these on-farm protocols to further minimize the need for antibiotic use.

Biosecurity – Prevent diseases by controlling traffic of pigs, people, vehicles and other items that can carry diseases into a herd, such as boots, coveralls and supplies.

- Apply all-in/all-out pig flow by site, or at least by room. See that workers honor this flow in their daily movements.
- Thoroughly clean, disinfect and heat/dry facilities or rooms between pig groups. This includes feeders, waterers and all other equipment.
- Limit pig commingling within a site as much as possible.



Vaccinations – Successful vaccination depends on targeted use of vaccines at the right time for the right health concern.

- Use diagnostics to confirm health issues.
- A vaccination program customized to your herd can help control and prevent disease.
- Administer the vaccine as outlined on the label.
- Store and handle vaccines correctly to ensure viability.

Environment – Provide the proper environment for the animals' age, weight and stocking density.

- Adjust ventilation systems to manage gases and humidity levels and to provide fresh air.
- Manage barn temperatures to meet pigs' needs.
- Eliminate drafts.

Management – Consider whether making certain management changes would further reduce the need for antibiotic use.

- Wean pigs at an appropriate age for the production system. Generally, weaning pigs older than a herd's average will produce a heavier, more robust pig in the growing phase.

Feed additives – So far, no antimicrobial alternative has proven as universally effective as antibiotics alone. Evaluate each alternative with your veterinarian for the application in question. As always, read and follow all label directions for any additives.

- Acidifiers, probiotics, essential oils may be options.
- Active proteins may help in young animals.
- Zinc and copper, which have antimicrobial properties, may be considered for swine.

Other Disease Strategies - A veterinarian can work to develop strategies to minimize disease risk through pig flows, herd health monitoring, disease surveillance and appropriate diagnostics.

- Work closely with your veterinarian to see where any of these other strategies can help manage overall pig health.

Don't forget about your farm employees, talk to them today about what lies ahead.

One Health Umbrella: Shared Responsibility, Opportunity to Combat Antibiotic Resistance

Since antibiotic resistance is a global concern, the worldwide "One Health" approach to combat antibiotic resistance is critical to human and animal health. This is a collaborative effort of multiple stakeholders to attain optimal health for people, domestic animals, wildlife, plants and the environment. Medical doctors and patients, veterinarians and farmers, along with government, academia and industry stakeholders, are cooperating. Pork producers play an important role in the shared effort to use antibiotics responsibly to help minimize the potential emergence of antibiotic resistant bacteria. In the end, this comprehensive and inclusive approach will create a win-win by protecting human and animal health.

To stay informed on the VFD and related regulations, bookmark pork.org/antibiotics— home of the Pork Checkoff's Antibiotics Resource Center—on your computer or smart phone. That's where you will find the latest information and resources about this important issue throughout 2016.