

Antibiotic CHANGES in Motion

Transformational Timeline

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

Guidance 213: On Dec. 11, 2013, FDA initiated the three-year transition process to complete its food animal antibiotic strategy. This includes animal health companies outlining 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 therapeutic use through VFDs for feed and prescriptions for water applications.

Proposed VFD Rule: On March 12, 2013, FDA concluded the comment period on its proposed Veterinary Feed Directive (VFD) rule. The agency will review and revise the proposed rule for veterinary oversight of medically important antibiotics. It will submit a final proposal to the Office of Management and Budget, and after approval, will issue the final VFD rule. This process sets the regulatory foundation for VFDs and could take a year or more.



The clock is ticking on the U.S. Food and Drug Administration's (FDA) proposed changes regarding subtherapeutic uses of medically important antibiotics (to treat human illness) in food-animal production. In fact, Dec. 12, 2013, began the three-year transition period for pharmaceutical companies to voluntarily remove any indicated production uses of certain antibiotics in food animals from their product labels. FDA's action also will eliminate over-the-counter sales of such medications.

"This is not a total ban of antibiotics in feed or water," said Liz Wagstrom, DVM, chief veterinarian for the National Pork Producers Council. "It will just affect the medically important ones and just for growth promotion. Antibiotic use for prevention, treatment and control of illness or disease will remain."

Producers will have to get a veterinary feed directive (VFD) to gain access to the covered feed-grade antimicrobials and a prescription for water-based products. This will require veterinary oversight and a diagnosis for a specific situation, which is FDA's driving objective.

"Pork producers routinely work closely with veterinarians, so this relationship is already part of their mind-set whenever they use antibiotics on the farm," said Jennifer Koeman, DVM, director of producer and public health for the Pork Checkoff.

"But, it will change how producers use these medications," Koeman said. "Although compliance will likely increase recordkeeping, time and costs to meet the VFD requirements, producers are committed to doing their part to ensure responsible antibiotic use on the farm."

continued on page 2

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continued from page 1

The pork industry already has two VFD products (tilmicosin and florfenicol), so at least some veterinarians, producers and feed mills will have experienced the process. Still, the list of products that will require a VFD or prescription has grown, involving the bulk of the major antimicrobial classes, Koeman said.

Products that will not be affected by FDA’s new policy include bacitracin, narasin, tiamulin, carbadox and bambermycin. Also worth noting, ractopamine is not affected because it is not an antibiotic.

“That has created some confusion when producers hear growth promotants are going away,” Wagstrom said. FDA is still working out some of the implementation

details, particularly related to the VFD rule. The agency has been collecting stakeholder comments for more than a year and wrapped up the process March 12 (See sidebar on page 1.) The VFD rule will affect anyone raising hogs, regardless of operation size or type.

“Whether you have show pigs, run a small operation or a large one, everyone will be affected,” Koeman said. “Also, all feed milling, on the farm or off, will be impacted.”

“Producers who make their own feed will have to have a VFD to buy the premix,” Wagstrom said. “And you’ll have to keep the records to prove that the usage is correct for the pigs and the batch of feed. It’s one more move in our history of continuous improvement.” 🍷

Take Time Now to Prepare

Officially, final implementation of FDA’s new regulations for the use of medically important antibiotics in food animal production is nearly three years off. However, we may see manufacturers of the affected antibiotics change their labels before this period ends.

“Producers should take time now to evaluate all the things they do to keep their animals healthy, including antibiotic use,” the Pork Checkoff’s Jennifer Koeman said.

Digging through the Details

The FDA will sort through the comments and work up the final VFD proposal, which means the details are still evolving. Here are some that are written into the proposed rules and are of particular interest to the pork sector:

- The expiration period for a VFD will be six months; 12 months for water-product prescriptions.
- A VFD will need to include the premises, species, production class, dose and duration. More clarification will be needed regarding how VFDs will cover pig flows and production site changes, but a VFD will estimate the number of animals to receive a feed prior to the VFD expiration.
- Veterinarians, producers and feed mills will have to keep VFD records for one year versus two required previously.
- VFDs will be able to be submitted through electronic orders, email, fax or other paper delivery. Verbal orders will not be an option.
- VFDs had applied to Category 2 medications, which were handled only by licensed feed mills. This will change to include unlicensed feed mills to accom-



modate accessibility.

- To offer more flexibility to veterinarians issuing VFDs than currently exists, the new rule will require veterinarians to retain oversight of the VFD process. This will require veterinarians to have a working relationship with producers as defined by the veterinary profession and the state veterinary licensing body. In the end, this may allow veterinarians to more effectively provide services to producers in remote areas.

Recommended Actions to Take Now

- Make sure you have a good working relationship with your herd veterinarian.
- Sit down with your veterinarian and review medications that you currently use.
- Review your overall animal-health protocols and the vaccination programs for your herd.
- Understand the VFD process so that implementation will be smooth.



PQA Plus® – Build Off the Basics

The Pork Checkoff's Pork Quality Assurance® Plus (PQA Plus®) program and producers' commitment to the We Care® ethical principles have long provided guidance for responsible on-farm antibiotic use. That won't change with FDA's new antibiotic use guidelines and the expansion of the veterinary feed directive (VFD) rule that covers more antibiotics.

Today, more than 60,000 producers have completed the PQA Plus on-farm education and certification program. All major packers require producers to participate in the program before they will purchase their market hogs.

PQA Plus' Good Production Practices (GPPs) continue to provide the basic platform for you and your employees to ensure responsible antibiotic use on the farm day in and day out.

"Particularly note GPP III, which outlines the principles of responsible antibiotic use," said Jennifer Koeman, director of producer and public health for the Pork Checkoff. "Producers have a long history of using antibiotics responsibly. With the PQA Plus principles already in place, we are well in line with the FDA strategy."

PQA Plus Basics

Principle I: Take appropriate steps to decrease the need for the application of antibiotics.

Principle II: Assess the advantages and disadvantages of all uses of antibiotics.

Principle III: Use antibiotics only when they provide measurable benefits.

Principle IV: Fully implement management practices described for responsible use of animal health products into daily operations.

Principle V: Have a working veterinarian/client/patient relationship and follow the responsible antibiotic use guidelines.



Other Tools in Your Toolbox

Antibiotics are an important tool in effective herd health strategies. While FDA's new guidelines will apply tighter restrictions on medically important medications, the agency has not outlawed their use.

"You still have access to these important tools," said the Pork Checkoff's Jennifer Koeman. "There will be some challenges on the farm, but producers can apply many other tools to boost herd health and minimize the need for antibiotics."

Han Stein, University of Illinois animal scientist, offers the following areas for renewed attention:

Biosecurity – Prevent diseases before they start, Stein said, with pigs getting diseases from other pigs, as well as vectors such as boots, coveralls and trucks.

- Apply all-in/all-out pig flow – preferably by site, but at least by room.
- Clean, disinfect and dry/heat facilities or rooms between pig groups.
- Never commingle pigs among sites and reduce commingling within a site as much as possible.

Vaccinations – Vaccines are an excellent tool in controlling and, in some cases, preventing disease.

- Successful vaccination depends on proper application so use vaccinations as recommended.
- Store vaccines correctly and ensure that they are still viable.

Environment – Provide the proper environment for 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.

Delay weaning – Weaning pigs between 21 and 28 days of age is the most economical, Stein said.

- Older weaned pigs require less medication and less need for specialized diets, thereby reducing costs.

Feed additives – Some have been moderately effective, some have not, according to Stein, with no alternative as universally effective as antibiotics.

- Acidifiers, probiotics, essential oils may be options.
- Active proteins may help in young animals.
- Zinc and copper, which have antimicrobial properties, may be options for swine.
- Each alternative is unique and should be evaluated for the pathogen or issue in question.

Inside: The pork industry prepares for FDA's upcoming changes in antibiotic use.



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Opportunity to Build Consumer Trust



"Pork producers are committed to supplying safe and wholesome pork products ..."

Julie Maschhoff,
The Maschhoffs, Carlyle, Ill.

The Food and Drug Administration's (FDA) veterinary feed directive (VFD) to change the way medically important antibiotics are used on the farm will affect pork producers nationwide. Whether you raise one pig or 100,000, you will need to acquire a VFD to use medically important antibiotics (for treatment of human illness) in feed or a prescription for water applications.

That is a significant change, but not an insurmountable one. FDA's new antibiotic policies are on pace to be fully implemented by December 2016. That gives pork producers, veterinarians and feed mills some time to prepare.

"We know that the new rules require additional recordkeeping and documentation for all our health protocols," said Julie Maschhoff, co-owner and vice president of public policy at The Maschhoffs, headquartered in Carlyle, Ill. "Whether we hire additional people or whether veterinarians hire more staff, there will be an increased cost for all producers."

She added, "Pork producers are committed to supplying safe and wholesome pork products, daily demonstrating the We CareSM ethical principles in our barns," Maschhoff said. "When it comes to on-farm antibiotic use, the public perceives that antibiotics are overused and contribute to antibiotic resistance. It's up to us to use these changes as an opportunity to stress how seriously we take our responsibilities as producers. If we can use this as a way to demonstrate our commitment to safe food, we will become a more trusted source of information for consumers."



This special-topic newsletter is sent periodically to you by the Pork Checkoff.

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