New Rules Issued for Antibiotic Use in Animals

Livestock producers and veterinarians will need to adjust to new voluntary guidelines affecting the use of antibiotics in food animals. On April 11, the Food and Drug Administration (FDA) released three documents (guidance 209, proposed guidance 213, and a veterinary feed directive draft text) impacting certain uses of medically important antibiotics in animal agriculture. Implementation of the policy means all medically-important antibiotics used in animal agriculture will be used only for therapeutic purposes — disease treatment, control, and prevention — under the supervision of a licensed professional. It will eliminate the use of medically important antibiotics for growth promotion and feed efficiency.

THREE-YEAR PHASE-IN PERIOD LIKELY

“I know producers are concerned about when they will no longer be able to use these products for subtherapeutic use in livestock. Based on our assessment of FDA’s proposed guidance 213, producers will have about three more years until the label changes occur from the time FDA finalizes guidance 213,” says Darrell Neuberger, DVM, with Pfizer Animal Health’s US Pork group in Iowa. “However, we are really encouraging producers to work with their veterinarians and us right now to create the alternative strategies that will ensure their herds remain healthy and productive.” Guidance 213 explains how drug companies can provide data to FDA to pursue therapeutic claims for these drugs.

The animal health industry has been generally supportive of the process. “In the face of many legislative proposals to simply ban products, FDA chose a collaborative stakeholder process to implement a policy that will phase out growth uses of medically-important antibiotics and phase-in veterinary oversight,” says Ron Phillips, vice president of public and legislative affairs for the Animal Health Institute. “That process is superior to legislative bans, in that it allows for an orderly transition by both animal health companies and producers.”

DISEASE PREVENTION IS THERAPEUTIC USE

The industry also appreciates that FDA recognized disease prevention as a judicious therapeutic use, as long as such use includes professional veterinary involvement. “Some people have issues with using antibiotics for prevention because you are giving it in the absence of apparent disease, but it is an extremely important label,” says Randall Singer, DVM, an associate professor of epidemiology at the University of Minnesota who researches foodborne pathogens and anti-microbial resistance. “Prevention involves giving antibiotics for a short term during a critical time when animals are highly susceptible to a disease. We know this reduces the incidence of disease and that having healthier animals leads to a healthier food supply,” he says.

“We support the guidance because we need to maintain long term access to these technologies for prevention, control and treatment of disease to ensure the food chain can continue to produce healthy animals,” says Colleen Dekker, global communications lead for Elanco Animal Health. “Healthy animals are the first link in the food safety chain and helps the entire chain deliver a safer product.”

Roger Saltman, DVM, group director for cattle and equine technical services at Pfizer Animal Health says, “The purpose of guidance 209 is not the absolute reduction of antimicrobial use in animals; the purpose is specifically to ensure that the use of medically important antimicrobial drugs is judicious. We don’t think that these rules will in any way impact our ability to maintain the health of animals.”

LIVESTOCK GROUPS CONCERNED

Several industry groups see challenges to adopting the rules. The National Pork Producers Council (NPPC) called FDA’s approach “problematic.” “We feel FDA took action with a low hurdle of scientific evidence and overlooked scientific risk assessments that show animal antibiotics result in an extremely negligible risk to public health,” says Liz Wagstrom, NPPC chief veterinarian. “We expect producers will see more sick pigs and a higher cost to produce those pigs without any anticipated benefit to public health.”

Livestock producers are also concerned that they will lose antibiotics that have been important to the health of animals for decades. “Some products are up to 50 years old and are off patent so we don’t know if drug companies will do the work to get them relabeled,” says Wagstrom.

Pfizer indicates it will consider the merits of seeking approval from the FDA of new therapeutic claims for these products on a case-by-case basis. Several of its products currently have approved therapeutic claims, and it will continue to market these products for these approved indications.

NEW APPROACHES NEEDED

Elanco Animal Health is looking at new alternatives and new platforms as well as different uses of existing technologies to advance animal health and productivity, according to Dekker.

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Minnesota Agricultural Education Leadership Council (MAELC) is a 16-member legislative council created in 1997 to reinvigorate agricultural education in Minnesota. It’s an umbrella organization for agricultural education, focusing on strengthening local programs at the secondary, post-secondary and farm management levels. MAELC is housed at the University of Minnesota alongside the Agricultural Education program. MAELC takes the lead on helping to develop new strategies to improve agricultural education in the state and region. The Council works with its stakeholders to look at new and innovative ways to increase its reach. To date, MAELC has awarded over $2 million in grants, scholarships, and special project funding.

Minnesota has 214 teachers in 185 secondary agricultural education programs, which reach nearly 30,000 students annually. There are also 65 farm business management instructors who work jointly with 3,000 farmers across Minnesota. MAELC works hand-in-hand with these teachers to help give them the tools needed to develop productive students and farmers.

The Council works cooperatively with the State of Minnesota, Minnesota Department of Agriculture, Minnesota Department of Education, University of Minnesota, Minnesota State College and Universities, Minnesota Association of Agricultural Education and the Minnesota FFA Foundation. MAELC is also looking at ways to include new partners in expanding programs to reach a larger audience.

Q & A with Sarah Dornink, MAELC Community Program Assistant:

How is your organization funded?
MAELC is fully supported by state legislative funding.

What is new with MAELC?
We are in a very exciting time for agricultural education in Minnesota. There is a renewed interest in learning about agriculture and we are continually asked about starting new traditional and non-traditional agricultural education programs.

New ideas are always being brought forward. We recently completed our first phase of a blueprint to provide a statewide plan for the next 3-5 years in Agriculture, Food and Natural Resource Education. This focuses on five areas including agricultural literacy, secondary education, 2-year post-secondary education, farm business management, and baccalaureate and above education.

Our secondary teachers are becoming better equipped with modern technology and learning mechanisms because of MAELC. The interest in teaching science and economics through agricultural curriculum has also expanded our programs. Success is proven through increased interest in classes and an increased number of students looking to study agriculture as a career at two- and four-year colleges and universities.

Finally, MAELC partnered with the Minnesota FFA Association to host the first annual Agricultural Policy Bootcamp. FFA members completed an application to attend the intense two-day camp held in January. Students had the opportunity to mingle with legislators at a legislative reception, testify in front of the House Agriculture Committee, be paired with a legislative mentor, and meet with Governor Dayton, Rep. Hamilton, and Sen. Magnus.

What are the key issues or trends affecting your industry?
Education is an evolving paradigm. MAELC works hard to include current stakeholders in expanding our curriculum and scope of activities, while trying to include new audiences. We are looking at ways to offer more inclusive programs across the state to work with emerging populations. There is a sincere interest in having agricultural education programs in both urban and rural areas. We provide excellent teaching and hands-on learning for students and feel all students in Minnesota should have access to our program.

We need to continue to recruit more students to pursue agricultural education careers to ensure that we have quality teachers offering quality programs. The trend of people being interested and involved in agriculture does not seem to be going away and want to make sure we reach students in a significant way and make a positive impact.

What are your legislative priorities?
We are being asked to educate more Minnesotans about agriculture. While class sizes are growing, there is increased competition from other courses. Having an increased number of classes mandated by the State (science, etc.) cuts down on the opportunities for students to take agricultural education courses or other electives. Our legislative priority is to make sure everyone who wants to be educated about agriculture is given the opportunity.

The Minnesota Agri-Growth Council is an advocate for the state’s food and agriculture industry. Founded in 1968, the Council is a nonprofit, nonpartisan organization that represents the shared interests of its 200-plus members, which include food and agriculture businesses, organizations and producers, as well as the service industries that support them.
The 2012 Legislative Session saw a handful of issues that had an effect on the food and agriculture industry. Some were in the form of bills or proposals that failed but could come back next year, and some issues were in buried in larger omnibus bills or in the form of amendments.

With the expiration of the 2012 session and sine die adjournment, any bills introduced over the past biennium would need reintroduction in 2013 for consideration. But before we begin to speculate on the 2013 session, we offer this post mortem on issues faced this session affecting the food and agriculture industry:

**State food safety enforcement; MDA civil penalties:** A three year process came to an end with the adoption of new consolidated food safety enforcement provisions including new civil penalties for adulterated, misbranded, and other illegal food sales. Originally part of this proposal, new requirements for inter-state food sales and commercial feed manufacturers were dropped due to the hard work of the Agri-Growth Council.

**GMO labeling:** A measure to require the labeling of foods containing genetically modified organisms (GMO) sold in Minnesota was introduced in the House this year but there were no hearings on the bill. The bill author attempted to add a new labeling task force as an amendment to the Omnibus Agriculture Policy Bill, but it failed on the House floor. The Agri-Growth Council is an ardent supporter of agriculture biotechnology and supports the position of the FDA that labeling would be misleading and is precluded since there is no nutritional or safety difference with non-GMO food ingredients.

**Raw milk:** Various bills this session would have liberalized the sale of raw milk into retail outlets in Minnesota, as opposed to the current authority limiting raw milk sales to farm premises only. The bills received an informational hearing, but did not advance through committees. Agri-Growth opposes any liberalization of raw milk sales due to safety, health, and image problems raw milk consumption could cause.

**Dairy research facility:** The Omnibus Agriculture Policy Bill authorized a public-private dairy production research facility that could bring promising and useful production and processing knowledge to Minnesota’s dairy and farming industry. The new dairy research facility would be managed and funded in cooperation with the University of Minnesota, Department of Agriculture, members of the Minnesota Milk Producers Association, and private industry partners.

**LFTB:** A measure requiring the labeling of lean finely textured beef (LFTB) treated with certain food safety interventions was successfully amended on to the Senate Omnibus Agriculture Policy Bill, before being stripped out in the conference committee at the request of the Agri-Growth Council.

**Antibiotics for livestock:** Bills proposing to ban certain antibiotics or meat products from animals treated with certain antibiotics were introduced over the biennium but did not advance through any committees or receive hearings.

**E-verify:** Governor Dayton vetoed a measure that would have required all new hires in state government to be checked through the E-Verify system that confirms whether an individual is legally authorized to work in the U.S. The Agri-Growth Council, along with the Minnesota Business Immigration Coalition, supports the enforcement of all labor and hiring laws, but opposes state and local intervention that add inefficient and duplicative processes to employers.

**Animal welfare:** No bills, provisions, or amendments were offered that would have restricted food processing companies or livestock farmers’ freedom to operate responsibly and safely. However, similar efforts – sometimes veiled as dog and cat breeding restrictions – advanced in other states and legislation was introduced in Congress to increase cage sizes for laying hens.

**Environmental permitting:** Measures were signed into law that would further streamline environmental permitting and Environmental Assessment Worksheets, and extend the length of State Disposal System permits for livestock operations from 5-years to 10-years.

The 2012 session and biennium comes to a close with many announced retirements of key legislators and other election match-ups that cast much uncertainty on 2013 and beyond. In the Minnesota Senate, we say goodbye to Agriculture Committee Chair Doug Magnus (R – Slayton), who is one of the few remaining farmers in the legislature. Other Senators with agriculture connections who will not be back next year include Keith Langseth (DFL – Glyndon), Gary Kubly (DFL – Granite Falls), and Gen Olson (R – Maple Plain).

In the Minnesota House, House members with agriculture connections who will not return next year include Ron Shimanski (R – Silver Lake), Kent Eken (DFL – Twin Valley); (running for Senate), and Lyle Koenen (DFL – Clara City); (running for Senate).

Whether Republicans or Democrats are in the majority in 2013, the agriculture industry will have its work cut out for it to make new friends, get reacquainted with old friends, and educate everyone about farm and food issues.

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Producers and veterinarians are going to have to be innovative in addressing the change in antibiotic availability, believes Jeff Bender, professor in the College of Veterinary Medicine at the University of Minnesota. This might include different management styles, probiotics, organic acids, vaccines, enzymes and zinc. “There will be economic and management impacts for producers, but I believe they will live up to the challenge and continue to produce high quality, safe food products,” says Bender.

Shayne Marker, DVM, at the Waconia Vet Clinic says, “If the FDA restrictions preserve the public’s trust in the food products produced by my livestock producers, that’s good. But I am concerned about animal welfare if drugs are taken away from us in the future based on outside pressure and not on sound science. We need the tools to keep animals healthy.”

**SHORTAGE OF RURAL VETS MUST BE ADDRESSED**

Another concern is how the veterinary oversight rules will affect small producers and those in remote areas with limited access to a veterinarian. FDA has issued an advanced notice of proposed rule-making for revision to the regulation dealing with the Veterinary Feed Directive (VFD) and is seeking comments and suggestions.

The VFD is a prescription like process in which a vet evaluates the need for a medicated feed additive for prevention, control and treatment of disease. Currently, only a few drugs require a VFD. The new rule proposes that veterinarians approve all medicated feed additives, even those currently available over the counter. “FDA has fixed some of the problematic issues such as allowing electronic signatures and allowing VFD orders to be written for a site instead of each group of pigs that goes through,” says Wagstrom. “But, the shortage of vets in rural areas is a very real concern for producers as is timely access to the drugs.”

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**New Rules Issued for Antibiotic Use in Animals, Continued from Page 1**

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“Producers are rightly concerned about the lack of availability of antibiotics they can use. This is the same issue on the human medicine side. We are seeing antibiotic resistance develop and we do not have a pipeline of new antibiotic drugs. That’s what is driving this action by FDA.”

— Jeff Bender, College of Veterinary Medicine at the University of Minnesota

Registration Open for Spring Events:

**LEGISLATIVE WRAP UP:** With the conclusion of the 2012 Legislative Session, join fellow food and agricultural industry stakeholders at the St. Paul Hotel on June 7 for the Agri-Growth Legislative Wrap Up. Find out what legislation passed and what didn’t, as well as what to expect for the 2013 session. Register online at legwrapup2012.eventbrite.com.

**ANNUAL GOLF TOURNAMENT:** This year’s Minnesota AgPAC Golf Outing will be held on June 11. The outing is an opportunity for agriculture and food industry leaders to network, while raising funds for the Minnesota AgPAC. Register online at agrigrowth.org/Golf.