Regulatory Services News

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Director's Digest- Fourth Quarter 2015

"Those who are ill informed about change will be at risk for a rough future." –Jason Canton

There will be many changes facing the agribusiness industry during the next two years and as the above quote indicates, failure to prepare for these can make doing business difficult. Implementation of the Food Safety Modernization Act (FSMA) will begin in 2016 and the Veterinary Feed Directive (VFD) will take full effect on January 1, 2017. These will require changes in how you do business and I would encourage you to make a New Year's resolution to start adapting early rather than later to these new laws.

We must remember that we are in a consumer driven business and ultimately must do what consumers want if we are to stay in business. FSMA is based on the FDA's desire to prevent rather than react to food safety issues as consumers want to be assured that their food, livestock feed and pet food are safe. The FDA did take to heart many concerns of the feed industry and change these rules to be more realistic than they were in the beginning but will still involve considerable changes in how you operate. There was a recent article in Feedstuffs that emphasized how you can use many components of FSMA to your advantage. Primarily, it gives management the opportunity to emphasize to their workers that the feed industry is part of the global food supply chain and underscore the importance of following procedures and completing required documentation. Any of you that have been involved in an FDA recall should certainly realize the benefits of preventing a recall from occurring but also the need for a plan to deal with one should it occur.

Whether you are a one man operation or a company with hundreds of employees, someone will need to be responsible for implementing FSMA. Some companies in Kentucky will need to comply with parts of this by September 2016 but most will have at least two years. The FDA is currently working on training for both industry and regulatory agencies but it is not too early to start preparing for these rules. If you manufacture medicated feeds, take time to thoroughly review the Feed Additive Compendium for current medication guidelines. Guidelines for commonly used products such as chlortetracycline and melengestrol acetate have changed over the last few years and it is better if you discover this now versus during an inspection. The Feed

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Additive Compendium also has a section on Current Good Manufacturing Practices (cGMP's) and this is the first part of FSMA to be implemented.

The Veterinary Feed Directive is intended to reduce the use of medically important antibiotics in livestock production in order to reduce microbial resistance to antibiotics in human medicine. Many of us may disagree with the methodology and can make a strong argument that more restrictions should be made on the medical profession. However, the die is cast and we must comply with the rules. If a reduction in microbial resistance does not occur, my fear is that we may have further restrictions on antibiotics in the future that will make them even more difficult to obtain. As a livestock producer myself, I do not like the restrictions this will place upon me but would prefer to still have feed grade antibiotics for prevention and treatment of illness than to have them taken away entirely.

The following antibiotics will require a VFD if used in feed and a prescription if used in water starting on January 1, 2017: Apramycin, Chlortetracycline, Erythromycin, Hygromycin B, Lincomycin, Neomycin, Oleandomycin, Ormetoprim, Oxytetracycline, Penicillin, Streptomycin, Sulfadimethoxine, Sulfamerazine, Sulfamethazine, Sulfaquinoxaline, Tylosin, Virginiamycin. We have made a laminated 11" x 17" poster listing these drugs that you can place at the sales counter (shown later in this newsletter). We would encourage putting this out in early 2016 so producers will be well aware of this rule and what antibiotics it involves before it takes effect. Also, the FDA has made some nice brochures tailored for producers, manufacturers, and veterinarians that you may want to have handy. Your Regulatory Services inspector will have a supply of the brochures and posters if you would like them. They are also available on our website in addition to other links to VFD information.

Implementing the FSMA and the VFD rules will not be easy and without cost but is not an option at this point. The earlier you can get started, the easier and less hectic it will be. I pledge that we at Regulatory Services will do what we can to help with this implementation and please don't hesitate to contact us with any questions you may have.

Darrell Johnson, Executive Director

Changes in Antibiotic Use in Animal Feed – What to Expect with new Veterinary Feed Directive Rules

Dr. Alan Harrison – Director Feed and Milk Programs

In December of 2013, the Food and Drug Administration (FDA) announced the implementation of a 3-year plan that will radically change the use of antibiotics in food animals. FDA uses the term "judicious use" to describe how they view the future of antibiotic use in animal agriculture. The plan focuses on the antibiotics used in both human and animals and the goal is address the issue of antimicrobial resistance while still keeping these drugs available to the feed industry. An increase in veterinary oversight for therapeutic use of antimicrobial drugs through the existing Veterinary Feed Directive (VFD) system is a major component of the plan. The final rule was published in June of 2015 and all regulations will take effect on **January 1, 2017**.

Only antibiotic drugs used in the feed and water of food producing animals are affected by the new regulations. Drugs included under new VFD guidelines include apramycin, chlortetracycline, erythromycin, hygromycin B, lincomycin, neomycin, oleandomycin, ormetoprim, oxytetracycline, penicillin, streptomycin, sulfadimethoxine, sufamerazine, sulfamethazine, sulfaquinoxalene, tylosin,

Continued next page

and virginiamycin. Drugs **not included** include ionophores (monensin and lasalocid), decoquinate, amprolium, carbadox, bacitracin, and flavomycin. These drugs are not used in human medicine.

How will antibiotic use change?
Basically, we use antibiotics in the feed industry in 4 ways:

Treating animals diagnosed with an illness
Controlling the spread of an illness
Preventing illness in healthy animals
Enhancing growth or improving feed efficiency

Antibiotics will still be available in feed (or water) for treatment, control and prevention of diseases. However, with the new regulations, all the medically important drugs will all require a VFD for use in feed or a prescription if used in water. These same medically important drugs will no longer be available for use to enhance growth or improve feed efficiency.

What are some examples of current feeds that will be affected?
Products still available but requiring a VFD: A preconditioning feed containing a combination of chlortetracycline and sulfamethazine and used to keep animals on feed after shipping. A milk replacer with neomycin and oxytetracycline. A feed or mineral product with chlortetracycline and lasalocid for control of anaplasmosis (CTC) and increased weight gain and efficiency (lasalocid). In the case of a product with a combination of drugs, if one drug is under a VFD, the combination is under a VFD.
Products that would no longer be available: A calf starter with a chlortetracycline level labeled for increased weight gain and improved efficiency. A beef mineral or supplement with chlortetracycline labeled for increased weight gain, improved feed efficiency, and reduction of liver abscesses. It is important to note that veterinarians would not be allowed to write an extra-label prescription for an antibiotic on the VFD list with an indication for use of growth promotion.

How do producers, veterinarians, and feed distributors work together to abide by VFD regulations?
Producer: Must work with a veterinarian licensed in the state where the animals are located to obtain a VFD for an animal or group of animals. Producer must also follow directions for feeding, must not feed after the expiration date, and maintain records for 2 years.
Veterinarian: Must be licensed to practice medicine and be in compliance with state requirements for an appropriate and valid veterinarian-client-patient relationship (VCPR). The veterinarian is responsible for preparing the written VFD (paper or electronic) with all required information including name of the VFD drug, description and location of the animals, and the length of the VFD (maximum of 6 months). Records must be maintained for 2 years.
Feed distributor: Must review the VFD for completeness and provide the feed only if all required information is provided. The feed distributor is also required to notify the FDA of their intention to distribute VFD feeds (one-time notification). As with the producer and veterinarian, the feed distributor must maintain records for 2 years.

In the past, decisions to use medication in animal feed were primarily made by producers and nutrition advisors with veterinarians playing a very limited role. Veterinarian involvement is now required if a medically important antibiotic is fed to a food producing animal. One positive aspect of these new regulations may be to improve the relationships between producers, veterinarians, feed distributors, and nutrition advisors.

Can the industry survive without the use of these drugs for growth promotion and feed efficiency?
Yes. Alternatives to the drugs we are losing are available including ionophores (monensin and lasalocid) and probiotic supplements. The gains made over the last few decades in animal production are not all attributable to the use of antibiotics in feed.

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Where can you find more information on the new VFD regulations?
Feedstuffs and Elanco have teamed up to develop an excellent website called VFD Central. This site provides articles, links to FDA publications, and webinars on the VFD regulations (http://feedstuffs.com/vfd.aspx). Our team at the University of Kentucky Regulatory Services will be actively involved in education of our Kentucky feed industry in preparation for the coming changes. One example of this educational effort is the development of a poster to be displayed in feed distributors with a list of VFD drugs and highlighting the regulatory changes coming in January 2017. We are also updating our website with links to the VFD Central website and other VFD web sites (http://www.rs.uky.edu).

FERTILIZER REGISTRATION FOR 2016 IN KENTUCKY

All Kentucky fertilizer registrations and licenses expire on December 31, 2015 and must be renewed to legally sell fertilizer in the state for 2016. Renewal notices to all current Kentucky registrants/licensees will be mailed at the first of December. The renewals list all products registered in the state for 2015, all licenses approved for 2015, and instructions for completing the task.

BE ON THE LOOK-OUT FOR YOUR RENEWAL NOTICE.

As always, if you have questions
Call: 859 257-2785,
Fax: 859 257-9478, or
E-Mail: June.Crawford@uky.edu

SURVEY OF COMMERCIAL VALUES OF FERTILIZER NUTRIENTS

Over the next few weeks you will receive or you may have already received a survey to determine the commercial values of fertilizer nutrients. Under the provisions of KRS 250.401, I am conducting a survey to determine the commercial values of the fertilizer nutrients for Calendar Year 2016. This survey is of utmost importance for the Division as well as the retail community of fertilizer sales. The values will be published and used in determining and assessing penalty payments if needed. Due to the fluctuating prices over the past several years it is important that we include as many surveys as possible. Our inspection staff will be asking if you have received and/or responded to this survey. Please note that we want the current retail value of fertilizers in dollars per ton. All information will, of course, be held in strict confidence. You can give the survey to your respective inspector or fax to 859-257-9478 to the attention of Steve McMurry or e-mail to smcmurry@uky.edu.

Last year's values are located on our website below:

http://www.rs.uky.edu/regulatory/fertilizer/index.php

Livestock Producers

Please be aware

The U. S. Food and Drug Administration has ruled that as of January 1, 2017 the following drugs will require a Veterinary Feed Directive (VFD) if added to feed. A prescription will be needed if used in water soluble form. The VFD or prescription must be provided by a licensed veterinarian.

Apramycin	**Penicillin**
Chlortetracycline	**Streptomycin**
Erythromycin	**Sulfadimethoxine**
Hygromycin B	**Sulfamerazine**
Lincomycin	**Sulfamethazine**
Neomycin	**Sulfaquinoxaline**
Oleandomycin	**Tylosin**
Ormetoprim	**Virginiamycin**
Oxytetracycline	

Information provided by:

UK UNIVERSITY OF KENTUCKY College of Agriculture, Food and Environment Regulatory Services

To learn more about the Veterinary Feed Directive please visit our website at:

http://www.rs.uky.edu

This poster will be available through your inspector or by contacting The Divison of Regulatory Services directly. All contacts are on page 2.

Fertilizer Official Sample Record

Stephen McMurry

July 1, 2014 thru June 30, 2015

The analysis of fertilizers for the fiscal year 2014 thru 2015 is now complete. These results were published in our annual regulatory bulletin and the full version can be found at the following link:
http://www.rs.uky.edu/regulatory/fertilizer/annual_bulletins/

Highlights of this past year are below:

Overall deficiency rate of all Official Samples	7.79%
Bagged samples deficiency rate	17.27%
Bulk sample deficiency rate	4.30%
Total tons sampled	53,378

Form	Type	Number of Samples	Samples of Total %	Tons Sampled	Tons Sampled of Total %	Sample Deficiency Rate %
Bag	Blended Grade	244	9	1,505	3	16.8
Bag	Manufactured	81	3	689	1	18.5
Bag	Material	5	0	32	0	20
Bulk	Manufactured	4	0	197	0	25
Bulk	Material	926	36	43,222	81	0.76
Bulk	Custom Mix	1252	48	5,855	11	6.87
Liquid	Blended Grade	55	2	1,143	2	14.54
Liquid	Manufactured	5	0	40	0	0
Liquid	Material	17	1	629	1	0
Liquid	Custom Mix	5	0	63	0	0

Regulatory Services News is published quarterly for the feed, fertilizer, milk and seed regulatory programs and the seed and soil service testing programs of the Division of Regulatory Services. It is provided free to persons interested in these programs. For subscriptions or address changes, contact our office at (859) 257-2785. You can also access and sign up for Regulatory Services News on the Internet at http://www.rs.uky.edu.

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