

Regulatory Services News

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Feed - Fertilizer - Milk - Seed - Seed Testing - Soil Testing
Ag Lime Testing - Industrial Hemp Testing

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Director's Digest

Keeping Current

It is easy to get caught up in our day-to-day duties and not keep up with new discoveries in our profession. Most professional organizations require their members to receive continuing education credits to maintain their membership. I belong to ARPAS (American Registry of Professional Animal Scientists) and am required to get 16 hours of continuing education each year to stay an active member. I mostly do this by attending the American Society of Animal Science annual meeting. Last year's meeting was virtual but this year we met in person in Louisville. This was the first meeting I have been able to attend in person since January 2020 and it was good to actually interact with people again. Attendance was down since some states are not yet allowing travel plus this was a joint meeting with the Canadian Society of Animal Science and the Canadians all had to attend virtually. Several presentations were done virtually, which did not always go well, but still a good meeting. I always enjoy hearing the perspectives of other animal science professionals and below are summaries of some topics I felt were particularly

interesting.

Greenhouse Gas Emissions

We have all seen the stories about how cattle are contributing to global warming through the production of methane. The University of California Davis is doing a lot of research in this area. If you have time, I highly encourage you to watch a video on You Tube about rethinking methane [Rethinking Methane - YouTube](#). Dr. Mitloehner points out in the video that while methane is a potent climate pollutant that we can and need to reduce, it warms our atmosphere differently than other gases because of its short lifespan. Carbon dioxide (primarily from fossil fuels) is a stock gas which means that what is produced today is stocked on top of what was produced yesterday and the day before and it lasts in the atmosphere for 1000 years. Methane is a flow gas in that as it is emitted it is also destroyed and only stays in the atmosphere for 10 years. Cattle are an integral part of recycling this carbon. Their research shows that if

Continued on page 3

What's Inside

Division Contact Information	2
Plant Variety Protection	4
Starting a Pet Treat or Deer Mineral Business . .	5
Responsibilities for Reporting Inspection/ tonnage Fees	6
Sample Compliance Enforcement	6
Medicated Feed – Responsibilities of the Man- ufacturer	7
ISO 17025 Update	9



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Director's Digest, continued

we can reduce the amount of methane emitted by cattle this can actually have a cooling effect on the atmosphere.

UC-Davis is doing exciting research in reducing methane production by cattle. They have tested several compounds that show promise. Past research in dairy cattle has shown that supplementing with seaweed (*Asaragopsis taxiformis*) has reduced methane production by fifty percent. Recently, researchers fed beef cattle 80 grams (3 ounces) of this seaweed over a five-month period. Cattle receiving seaweed gained as much as their herd mates while burping out 82 percent less methane.

I find it very satisfying to work in an industry where researchers continually seek answers to the problems we face.

Food Industry Survival during the Pandemic

We all experienced shortages of foods, especially meats, during the height of the pandemic in 2020. Covid-19 pandemic related precautions and workforce illness caused multiple packing plants across the country to decrease or stop production in the spring of 2020. This resulted in feedlots being unable to ship cattle at optimal finish points. Estimates of the number of cattle backlogged approached one million. Feedlots were faced with decisions on how to manage finished animals that could not be shipped while considering economic, animal welfare, and animal health outcomes. Many factors further complicated the situation including highly volatile markets, the possibility of employee quarantine due to personal or family illness that would cause operations to be under-staffed, and shortage of available pens for new cattle. Feeders had the option to slow the growth rate of cattle by using more roughage in the diet but roughage is not readily available in many feedlot areas. Another option was to limit feed cattle the current diet to slow growth while making sure cattle receive

enough feed to be satisfied. Many feeders chose to continue pushing for maximum gains and hope persistent growth and feeding margins would offset discounts due to heavy carcass weights and excess fatness when the supply chain began moving again.

Most beef producers in Kentucky are cow-calf and/or stocker operators. We rely mostly on pasture or hay and never had to change our rations during the pandemic. It was interesting to hear the challenges faced by the finishing end of the beef business. It is encouraging how quickly the industry adapted as meat was not out of the stores for a long period.

On a related note, the pandemic strengthened the desire of many consumers to buy local. This includes meat. As a result, many slaughter facilities in Kentucky are backed up and waiting lists to have animals slaughtered are eighteen months or longer. Politicians have taken note and are providing money for new slaughter facilities or for improvements/expansion of current facilities. State funding in 2020 to small and medium slaughter facilities totaled \$87.6 million for 17 states, including \$4.9 million in Kentucky. Missouri had twenty-six new small slaughter plants go on-line in January of this year but the state government doesn't have the inspection staff to cover this many facilities.

We can certainly use more slaughter facilities in Kentucky but I think most consumers would prefer their meat be properly inspected for food safety so we don't need to grow too fast too soon. Two concerns raised by this presenter in regards to expansion of small slaughter facilities were:

- Will people continue to want local beef as we move further from the pandemic?
- Will politicians continue funneling money to local slaughter facilities as we move further from the pandemic?

Continued on page 4

Beef on Dairy

I have watched with interest the relatively recent push to breed dairy cows to beef bulls. With the advent of sexed semen, I understand that dairy heifers are plentiful and we can improve the quality of surplus dairy animals going to the feedlots by bringing in some beef influence. However, I have worked with several extension dairy reproduction specialists over the last 40 years and know many of them must be cringing at the thought of breeding a dairy cow/heifer to a beef bull.

This trend has really picked up since 2018 to the point that more beef semen is now sold to dairies than to beef operations. Beef semen sales since 2017 are shown below:

- 2017: 2.5 million total units
 - ◊ +3.9% from the previous year
- 2018: 4.0 million total units
 - ◊ +58.4% from the previous year
- 2019: 5.8 million total units
 - ◊ +44.4% from the previous year
- 2020: 6.6 million units

There is still lots of discussion on what crosses work best from growth and marketing standpoints. It is suggested that with the reduced cost of embryo transfer, the next trend will be to bypass the insemination step and transfer beef embryos directly into dairy cows.

It was refreshing to attend an “in person” meeting again and I enjoy learning about the newest research. Hopefully, each of you find a way to stay up on new developments in your chosen profession.

*Dr. Darrell D. Johnson,
Executive Director*

Plant Variety Protection

The U.S. Department of Agriculture’s (USDA) Agricultural Marketing Service (AMS) helps ensure the quality and fair marketing of U.S. agricultural products. Plant breeders use plant variety protection as an important marketing tool that protects their innovation. The AMS Plant Variety Protection Office (PVPO) provides intellectual property rights protection to breeders of varieties of sexually reproduced, tuber propagated and asexually reproduced plants that are new, distinct, uniform, and stable.

new, in that on the date of filing of the application for plant variety protection, propagating or harvested material of the variety has not been sold or otherwise disposed of to other persons, by or with the consent of the breeder, or the successor in interest of the breeder, for purposes of exploitation of the variety;

distinct, in that the variety is clearly distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge at the time of the filing of the application;

uniform, in that any variations are describable, predictable, and commercially acceptable; and

stable, in that the variety, when reproduced, will remain unchanged with regard to essential and distinctive characteristics of the variety with a reasonable degree of reliability commensurate with that of varieties of the same category in which the same breeding method is employed.

The unauthorized reproduction of protected varieties is strictly prohibited. Some of the infringing activities of protected varieties include, but are not limited to, selling, marketing, offering for sale,

importing, exporting, producing and reproducing the protected variety. Those who infringe on the rights of a PVP protected variety may be liable for damages up to three times the amount of the reasonable royalty of the PVP holder as well as additional state statutory damages.

If you are not sure if your seed may be a protected variety you can often check the bag or tag labeling, refer to your limited use/technology use agreement, review the seed company website, or talk with your seed supplier for details on the purchased variety.

The information above and additional information can be found from the Seed Innovation & Protection Alliance at www.seedipalliance.com and from the USDA Agricultural Marketing Service www.ams.usda.gov/services/plant-variety-protection.

*Stephen McMurry,
Fertilizer and Seed Program Director*

Starting a Pet Treat or Deer Mineral Business in Kentucky

Are you thinking about making your own pet treats to sell at farmers' markets this summer? Or maybe you've developed a great formula for a deer mineral that you are ready to market? You should be aware that the Kentucky Commercial Feed Law and Regulations requires these products to be registered with the University of Kentucky Division of Regulatory Services. We know that getting started can be tough, though, so we have put together resources to help you through the registration process.

In general, product registration information can be found here: <http://www.rs.uky.edu/regulatory/feed/registration.php>. The basics of registering your product(s) with the Division include: (1) an application form, (2) a copy of the label for each product, and (3) \$50/product payment only if the product is going to be sold in package sizes exclu-

sively 10 lbs or less. Our Division has examples of labels for pet treats, pet foods, deer minerals and deer feeds (http://www.rs.uky.edu/regulatory/feed/feed_labels/). These brochures explain the general formatting and required information that must appear on product labels.

One of the ways our Division can help is by estimating the guarantees that are required to appear on the label. If your formula is fairly simple, using estimated guarantees may be a good, cost free option. If you wish to utilize this service, email your formula (ingredients and amounts - these are kept confidential) and a general description of your type of product (e.g. baked dog biscuit, deer mineral, etc.) to ukfeed@uky.edu. If your product includes pre-mixes, you must submit a legible copy of the guaranteed analysis and ingredient list for each premix used. If you submitted a pet treat formula, you will also receive a calorie content estimate. Please note that our Division stays pretty busy so it may be a little while before you hear back.

If your formula is very complex, or contains uncommon ingredients, it may be easier to send a sample of your product to our lab to have it analyzed for the required guarantees. The Division offers a limited analysis service to Kentucky citizens and businesses on a per request basis. If you are interested in having our office analyze your product sample, please contact ukfeed@uky.edu. Alternatively, you can always send a sample of your product to a commercial lab and have them analyze for the required nutrients or you can try our online Feed Tag Guarantee Estimator (left hand link on <http://www.rs.uky.edu/regulatory/feed/>) yourself.

Once you have your estimated guarantees, take a look at the labeling examples offered at the link further above and put together a draft label. We recommend that you send in a draft label with your registration application and fee (if required), not your final printed label, because we often require changes and we don't want to see you spend money

Continued on page 6

on labels you can't use. Once you've heard back from our office that your label is accepted, your product is registered and you are all set to sell your product in Kentucky. If you plan to sell in other states, you can find out who to contact for more information here: <https://www.aafco.org/Regulatory/State-Information>.

Good luck and always feel free to contact us at ukfeed@uky.edu with any questions.

*Kristen Green,
Registration Specialist*

Responsibilities for Reporting Inspection/tonnage Fees

The Kentucky Commercial Feed Law and Regulations stipulates that quarterly inspection/tonnage fees must be paid for large package commercial animal feeds. For firms or individuals that have another firm manufacture their product, the firm responsible for paying the inspection/tonnage fees can get confusing. At the Division of Regulatory Services, we look at the submitted label, and whoever is listed as the guarantor on the label is entered into our registration system with that product listed under their account. That guarantor is then required to pay the inspection/tonnage fees.

If your firm has arranged for the manufacturer or another firm to pay your firm's inspection/tonnage fees, it must be reported and paid separately from the manufacturer's other tonnage. A separate tonnage form will be created and emailed/mailed. It cannot be included in the manufacturer's normal tonnage reporting. Additional information and a tonnage FAQ can be found here: <http://www.rs.uky.edu/regulatory/feed/tonnage.php>.

*Kristen Green,
Registration Specialist*

Sample Compliance Enforcement: Withdrawals from Distribution

In the Spring 2021 issue of our newsletter, I mentioned that the Feed Program would begin issuing withdrawals from distribution this summer when select analytes failed to meet their label guarantees. This article will dive a little deeper into this policy and what guarantors can expect.

Under KRS 250.531 and KRS 250.591(1), we have the authority to issue a withdrawal from distribution for any product that fails to meet label guarantees. Our analytical variations for each analyte are published in our regulations (12 KAR 2:021, Section 10) and are also available on our website.

KRS 250.531: A commercial feed shall be deemed to be misbranded: 1. If its labeling is false or misleading in any particular.

KRS 250.591 1. When the director has reasonable cause to believe any lot of commercial feed is being distributed in violation of any of the provisions of KRS 250.491 to 250.631 or of any of the prescribed administrative regulations under KRS 250.491 to 250.631, he may issue and enforce a written or printed "withdrawal from distribution" order, warning the distributor not to dispose of the lot of commercial feed in any manner until written permission is given by the director or the court.

Our typical action when a sample fails to meet a label guarantee is to send the report along with the Manufacturer's Report on Investigation of Label Violation to the guarantor and the plant (if known). The withdrawal from distribution has always been on the table but we have used this sparingly in the past several years.

Beginning with samples collected after July 1, our feed program will begin utilizing the withdrawal from distribution option more frequently. For select analytes (**non-protein nitrogen, salt, copper, selenium, and all medications**), we will issue withdrawals from distribution for all sample violations. We will continue to use discretion in issuing withdrawals from distribution when samples fail for rea-

reasons other than the aforementioned analytes. We chose these particular analytes because deficiencies and excesses can have a negative impact on animal health and performance.

In addition to the sample report, the guarantor, dealer, and plant will receive a withdrawal from distribution notice. The dealer will be asked to remove the product in question from distribution and the guarantor and/or plant will be required to respond to the Feed Program. If necessary, we will provide assistance to the guarantor/plant in the disposition of the product and the resolution of the stop sale.

*Dr. Alan Harrison,
Director Feed and Milk Programs*

Medicated Feed – Responsibilities of the Manufacturer

When addressing issues involving law and regulation, we generally stick to our own Kentucky statues and regulations. However, federal regulations also must be followed when producing animal feed. Federal regulations regarding medicated feed are quite specific and can be complicated. I will attempt in this article to simplify some of these regulations and explain how they apply to FDA inspections of medicated feed mills.

Regulations applying to licensed medicated feed mills

21 CFR 225 covers both licensed and non-licensed medicated mills. 225.10 to 225.115 applies only to licensed mills - facilities manufacturing one or more medicated feeds for which an approved medicated feed mill license is required. Currently, we have 8 licensed mills in Kentucky with 3 of these mills producing commercial feed. Licensed mills are very familiar with the assay requirements in 225.58. At least 3 samples of medicated feed containing each drug used must be tested each year. The assay limits are published in the Code of Federal Regulations (21 CFR 558.4(d)). A selection of assay limits on medications is included in the table at the end of this arti-

cle. Documentation of these assays for medication, regardless of results, is required and must be maintained for not less than a year after distribution of the feed. During inspection under FDA authority, management will be asked to provide documentation showing the history of these assays. If any of these samples fail under federal assay limits, there are additional requirements of investigation and corrective action documentation.

Licensed mills may not be aware that results of state samples may also be used to meet the assay requirement. Again, if any of these samples have a medication level that falls outside the federal assay limits, documentation of investigation and corrective action is required.

Regulations applying to non-licensed medicated feed mills

Currently, there are 44 non-licensed medicated mills in Kentucky producing commercial feed. 225.120 to 225.202 applies only to non-licensed mills - facilities manufacturing one or more medicated feeds but not using medications for which an approved medicated feed mill license is required. There are no assay requirements for non-licensed mills. However, if a medicated feed is tested and if the medication does not meet federal assay limits, the manufacturer is required to investigate and implement a corrective action plan. As with licensed mills, records of the failed sample results, investigation, and corrective action must be kept for one year and made available during inspection under FDA authority.

Kentucky analytical variations (AV's) versus FDA assay limits

The table lists five medications that are currently run in our lab. Our Kentucky AV's are identical to FDA assay limits for chlortetracycline, decoquinatone, and lasalocid. Compared to the FDA assay limits, our AV's are more generous on the low side

Continued on page 8

for amprolium (-40% vs. -20%) and on the lower and upper for monensin (-30/+30% vs. -15/+15%). FDA limits for monensin actually differ for birds (chickens, turkeys, quail) compared to ruminants (beef and goats). I used the beef and goat feeds limits in the table since monensin in beef and goat feed is far more common in Kentucky. Using a beef feed with a guarantee of 30 g/ton monensin sampled by one of our inspectors, here are the possible outcomes:

Sample test finds 29 g/ton. This sample passes under both Kentucky and FDA regulations. For a non-licensed manufacturer, no action is required and no records need be kept. For a licensed manufacturer, these sample results should be kept for at least 1 year and can be used to fulfill the assay requirement under 225.58.

Sample test finds 20 g/ton. This sample fails under both Kentucky and FDA regulations. Under Kentucky policy, our office will issue a withdrawal from distribution and expect a prompt response. Both the licensed and the non-licensed mill should conduct an investigation, formulate a corrective action plan, and keep records for at least 1 year that would be available during an inspection under FDA authority.

Sample test finds 23 g/ton. This sample passes under Kentucky regulations but fails under FDA regulations. No withdrawal from distribution would be issued by our office. However, both the licensed and the non-licensed mill should conduct an investigation, formulate a corrective action plan, and keep records for at least 1 year that would be available during an inspection under FDA authority.

We realize that complying with both state and federal regulations can be challenging and differences in these regulations add an additional layer of complication. I will be sending reminders with any medicated feed sample results that fail under Kentucky or federal regulations and we are always available to answer questions.

21 CFR 225.1 Current good manufacturing practice.

(2) The regulations in §§ 225.10 through 225.115 apply to facilities manufacturing one or more medicated feeds for which an approved medicated feed mill license is required. The regulations in §§ 225.120 through 225.202 apply to facilities manufacturing solely medicated feeds for which an approved license is not required.

21 CFR 225.58 Laboratory controls.

(b) The following assay requirements shall apply to medicated feeds:

(1) For feeds requiring a medicated feed mill license (Form FDA 3448) for their manufacture and marketing, at least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed by approved official methods, at periodic intervals during the calendar year, unless otherwise specified in this chapter. At least one of these assays shall be performed on the first batch using the drug. If a medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested.

(c) The originals or copies of all results of assays, including those from State feed control officials and any other governmental agency, shall be maintained on the premises for a period of not less than 1 year after distribution of the medicated feed. The results of assays performed by State feed control officials may be considered toward fulfillment of the periodic assay requirements of this section.

(d) Where the results of assays indicate that the medicated feed is not in accord with label specifications or is not within permissible assay limits as specified in this chapter, investigation and corrective action shall be implemented and an original or copy of the record of such action maintained on the premises.

21 CFR 225.158 Laboratory assays.

Where the results of laboratory assays of drug components, including assays by State feed control officials, indicate that the medicated feed is not in accord with the permissible limits specified in this

chapter, investigation and corrective action shall be implemented immediately by the firm and such records shall be maintained on the premises for a period of 1 year.

UKDRS analytical variations for medicated feed samples (12 KAR 2:021) and FDA assay limits (21 CFR 558.4)				
	Lower AV	Upper AV	FDA Assay Limits	
Amprolium	-40%	20%	-20%	20%
Chlortetracycline	-30%	30%	-30%	30%
Decoquinatate	-20%	20%	-20%	20%
Lasalocid	-25%	25%	-25%	25%
Monensin	-30%	30%	-15% ¹	15% ¹
¹ Beef and goat feed				

*Dr. Alan Harrison,
Director Feed and Milk Programs*

We Did It Again! (ISO 17025 update)

We recently had our Surveillance Assessment from our Accreditation Body, American Association for Laboratory Accreditation, to the ISO/IEC 17025:2017 International Standard. In addition to reviewing our Quality Management System and previous deficiencies, we added 4 more methods to our Scope of Accreditation. Now we have 13 methods and 31 analytes on our Scope of Accreditation! This is further evidence that we, at UKDRS, meet the technical competence for the methods on our scope and successfully operate a laboratory quality management system! I am so proud of everyone's hard work and cooperation!

This further demonstrates the dedication and professionalism of the staff at UKDRS. Our plans are to continue adding to our Scope of Accreditation and maintaining our ISO 17025:2017 Accreditation status.

What does it mean to "maintain" our accreditation status? We have to ensure that quality objectives and scope of activities are defined and

make sure responsibilities and authorities are assigned. One way we do this is by performing internal audits of each technical and quality standard operating procedure. We currently have a schedule of when we perform the audits on our standard operating procedures so that in a 12-month period each will get reviewed.

For our audits of methods, the main goals are to make sure we are doing what we say and saying what we do. Another is to verify that our personnel performing the method is trained and competent. We also make sure that the environment that the test is performed is still meeting our expectations. We discuss the method with the analyst to see if there are any improvement ideas for the method or for the work-flow. We make sure that the method has been verified or validated. We review data and quality reference materials to make sure that the calculations are still correct. Along with that we evaluate that the measure of uncertainty is the same or if it's

Continued on page 10

changed, why? We make sure that the equipment we use for the method is operating correctly and that the reagents and chemicals are the correct quality, concentrations, and traceable.

When evaluating our quality standard operating procedures, we make sure that our quality management system is meeting UKDRS' policies, commitments, regulatory requirements, our accrediting body requirements, and ISO 17025:2017 policies. Each administrative, instrument, laboratory operation, and quality standard operating procedure gets evaluated each year.

During our annual management review, we review changes relevant to the laboratory, verify that we meet our objectives outlined in our quality manual, and the suitability of policies and procedures. We also review the status action items from the previous management review. We review the outcomes of internal audits. We also evaluate corrective actions and their effectiveness. Assessments by external bodies, changes in the volume and type of work or in the range of laboratory activities, customer and personnel feedback, and complaints. We review the effectiveness of any implemented improvements, adequacy of resources, validity of results, and other relevant factors, such as monitoring activities and training. We also review the results from risk identifiers and review the risk registry of all potential risks.

We are continually evaluating our operations, policies, and standard operating procedures so that we provide unbiased quality results for our customers. We are continually looking for ways to improve our quality standards. We will continue to improve so that our consumers, stakeholders, and farmers are protected.

Sharon F. Webb, Ph.D.
Director, Quality Program

Upcoming Meetings

AAFCO 2021 Summer Annual Meeting-Virtual

August 2-4

[The Association of American Feed Control Officials > Meetings > Annual > 2021 \(aaafco.org\)](https://www.aaafco.org/Meetings/Annual/2021)

University of Kentucky Beef Bash

C. Oran Little Research Farm

Versailles, Kentucky

October 14, 2021

BEEF.

IT'S WHAT'S FOR DINNER.®

FARMABLE LAND

Approximately 29% of the land in the U.S. is pasture and rangeland that is too rocky, steep and/or arid to support growing food crops - yet cattle can graze on this land and convert grass to protein.



Source: USDA, Economic Research Service using data from the Major Land Use data series. Available at: <https://www.ers.usda.gov/data-products/major-land-uses.aspx>



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