

Regulatory Services News

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

Winter 2021

Director's Digest

Endeavor to Persevere

We are now nineteen months into the Covid pandemic and we have seen our fair share of ups and downs. Things were looking up back in the spring and many mask mandates went away including those in our building. However, here came the Delta variant and mask mandates were reinstated including on the UK campus where they are still in place for the foreseeable future. On the bright side, UK students returned to campus this fall along with more in-person classes and there seem to have been few issues. Vaccination rate on campus, now required, is at 89% and this has certainly helped.

As I mentioned in the last newsletter, in-person meetings have returned but attendance is down compared to pre-pandemic. I've had several more meetings in the last three months and attendance has been at about 50-60% compared to prior years. Fear of Covid is the reason most often given by those deciding not to attend. I've even had a few meetings that were scheduled to occur in-person back in early summer but were either canceled or switched to Zoom as the Delta variant reared its ugly head. Amazingly,

having a good football team must help override the fears of infection as the last two UK football games have been sellouts and so is the next one scheduled in early November.

We have certainly faced many disruptions in our economy in the last nineteen months. We still see many businesses having trouble finding employees and are seeing shortages of many different things in our retail stores including agricultural retailers. As noted in another article in this newsletter, we are facing spikes and potential shortages of important inputs such as fertilizer and seed. We are seeing increased prices for almost all consumer goods and don't even get me started on fuel costs.

There are many theories offered as to why our supply chain is broken. Factory shutdowns overseas due to COVID, cargo ships being backlogged at US ports, shortages of truck drivers, shortages of retail and warehouse workers to stock shelves, etc. In addition to supply chain issues, there is ample evidence that US consumers are buying everything they can get their hands on. I have not tried to purchase a

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Director's Digest, continued

year's supply of toilet paper but I did have a minor panic attack when I couldn't find glyphosphate at my local retailer and heard it will be in short supply next season. I admit that I went online and purchased some even though I will have no use for it until late next spring.

I am a big Clint Eastwood fan and one of my favorite movies of all time is "The Outlaw Josey Wales". In that movie, an Indian chieftain played by the great Chief Dan George, explains to Josey a meeting that many of the Indian chieftains had with leaders in Washington, D.C. where they were told to "endeavor to persevere". That phrase has crossed my mind a lot during the last several months as we continue to deal with pandemic issues.

I recently read an article on how our economy quickly recovered from the Spanish Flu epidemic that was almost exactly 100 years ago. We had survived a world war, two recessions in quick succession, a pandemic, and a period of extreme domestic unrest. The recovery in the early 1920's was led by electrification and mass manufacturing attributed largely to Henry Ford. This article suggested that potential solutions to our current pandemic issues are vaccines and treatments to make Covid-19 impotent and improvements to our infrastructure, especially expanding 5G broadband access across the country. I'm not sure what the answers will be but am confident that if we truly endeavor to persevere, there will be a bright future when this is over.

When the shoe is on the other foot

Dr. Stuart Smyth is an Associate Professor of Agriculture at the University of Saskatchewan and a long-time defender of biotechnology. He noted in a recent blog that biotech developed crops, fruits, and vegetables have been approved for production following over 4,400 risk assessments by government scientists in over 70 countries. Over the last

25 years, no adverse health effects have been proven from utilizing these crops but deliberately misleading information still abounds on social media. The objective of misinformation is to scare, persuade, and instill fear into individuals about consuming perfectly safe products.

Political parties in many countries have contributed to the spread of misinformation about biotech foods and mainstream media has collaborated in spreading misinformation by airing programs that included untrained activists claiming to be experts, when the reality is that they have no formal training or expertise to back up their accusations of harm and danger.

Now along comes 2020 and the need to develop a Covid vaccine rapidly. This work was carried out by biotech companies, and the Covid vaccines we have are also biotech products, having been developed by innovative genomic sciences. Similar to GM foods, biotech vaccines have redefined the next stage of their industry and opened up opportunities.

As vaccine rollouts began in 2021, the misinformation about the safety of Covid vaccines steadily increased. False and incorrect information has been spread by anti-vaccination groups, organizations, and social media influencers. Politicians and mainstream media have become very frustrated with the spread of this misinformation. Ironical, since many of them are the same ones who have spread misinformation about biotech foods. Dr. Smyth concludes with the thought that *"it would be refreshing, although completely unlikely, for politicians and the media that have publicly opposed biotech foods, to now stand up and publicly admit they were wrong about the safety of biotech products, be they vaccines or foods."*

***Dr. Darrell D. Johnson,
Executive Director***

Inspections under Food Safety Modernization Act Regulations: An Update

Early in 2020, I discussed our division plans for inspections under the Food Safety Modernization Act (FSMA) for the coming year. As the old saying goes, “man plans and God laughs”.

For our 2020-21 contract with FDA, we had planned on a total of 28 inspections with 10 of these including Hazard Analysis and Risk-Based Preventative Controls (PC’s) under 21 CFR Part 507 Subpart C. Between restrictions and concerns with COVID, we were able to complete 23 inspections with only four of these covering the PC regulations. As we return to something approaching normal, our 2021-22 plans are to conduct a total of 32 inspections of which 12 will include coverage of the PC regulations. Currently, our division has 4 inspectors trained to conduct the PC inspection. An additional 4 inspectors are scheduled to be trained in the coming months.

To review, all facilities, regardless of size, that manufacture, process, pack, or hold animal food need to comply with Good Manufacturing Practices (GMP’s) regulations covered under 21 CFR Part 507 Subpart B. Good manufacturing practices are about making feed that is safe for the intended purpose and not contaminated. The other half of FSMA regulations involve Hazard Analysis and Risk-Based Preventative Controls (PC’s) under 21 CFR Part 507 Subpart C. Developing and implementing a Food Safety Plan is a requirement of these regulations. Firms are responsible for evaluating potential or foreseeable hazards in feed and putting controls in place if hazards exist.

The regulations exempt a “qualified facility” from the PC portion of the regulations (21 CFR Part 507 Subpart C). The majority of firms that manufacture animal feed and that are exempt from the PC regulations are those that FDA defines as a “very small business”.

Part 507 defines “very small business” as a business, including any subsidiaries and affiliates, averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufac-

tured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).

Our estimate is that about 60-70 of the 190 feed manufacturers in KY would be eligible for the PC inspection. Firms can file an exemption with FDA and around 20 or so KY firms have done so. However, current FDA policy is that the filing of an exemption is not what determines if a firm is or is not eligible for the PC portion of the inspection. In other words, if the firm fits the definition of a very small business, they would not fall under the PC portion of FSMA regulations. When our inspectors show up to conduct a contract inspection, they will know what regulations will be covered.

FDA’s philosophy regarding inspections has shifted to covering more regulations with fewer inspections. Our inspectors are responsible for covering all federal regulations related to production of animal feed during a single inspection. All manufacturers would fall under 21 CFR Part 507 Subpart B and all inspections will include the FSMA cGMP regulations. And if the firm is eligible, Hazard Analysis and Risk-Based Preventative Controls (PC’s) under 21 CFR Part 507 Subpart C One are also included. If the firm produces medicated feed, they will cover 21 CFR Part 225 regulations for either a licensed or a non-licensed mill. An inspection for compliance with the ruminant-to-ruminant feed ban (21 CFR 589.2000 & 2001) would be conducted if the firm handles prohibited protein (the BSE inspection).

On the upside, firms can expect to see FDA or state inspectors under FDA authority less often for inspection purposes. On the downside, it means more time necessary per inspection visit. If a medicated feed inspection is included along with a Part 507 cGMP, we will send 2 inspectors and they will spend at least a full day or two half-days on inspection time including interviews and record review. The addition of the PC inspection may add another half day. Inspections that go well, go quickly. Those that don’t always take longer.

If you have any questions about what you can expect during any of these inspections, please contact your local inspector or our office.

Dr. Alan Harrison,
Director Feed and Milk Programs

Survey of Commercial Values of Fertilizer Nutrients

Our survey of commercial values of fertilizer nutrients will go out in early December. Under the provisions of KRS 250.401, I am conducting a survey to determine the commercial values of the fertilizer nutrients for Calendar Year 2022. 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. It is important that we include as many surveys as possible. Our inspection staff will be asking if you have received and/or re-

sponded 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>

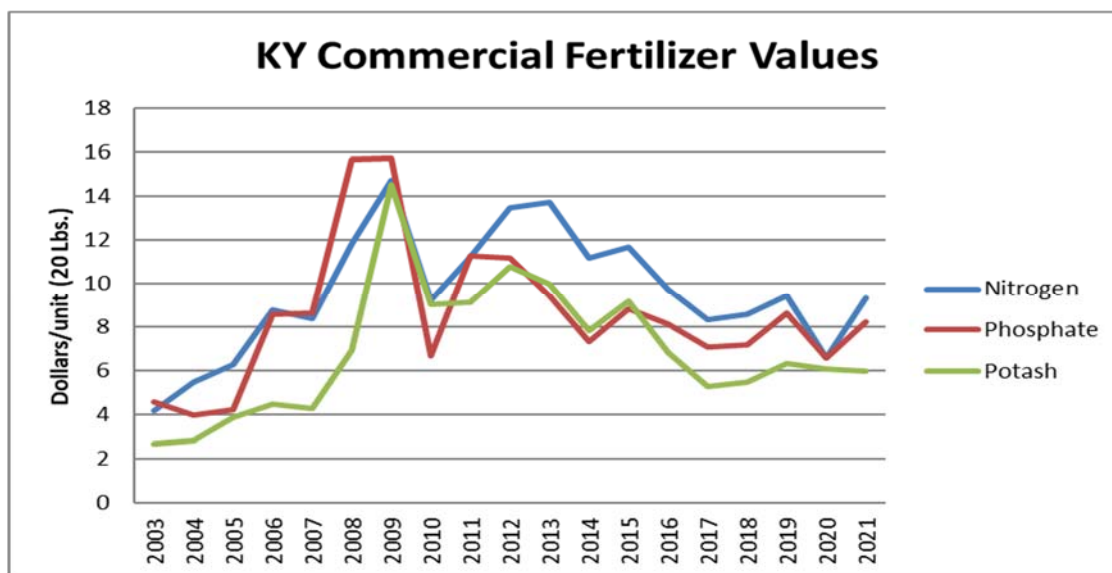
Stephen McMurry,
Fertilizer and Seed Program Director

Fertilizer and Seed Prices are on the Rise

For the past few months I have been hearing how fertilizer and grass seed prices are on the rise. As a regulatory agency we do not spend a lot of time in regard to the analysis of commodity prices, but are aware of the year to year changes. So each December the fertilizer program sends out surveys to the fertilizer dealers within KY to find out the commercial values of fertilizer nutrients which we utilize to determine penalties of deficient fertilizer products for the next year. The graph below is of the past 18 years of data for Nitrogen, Phosphate and Potash

from these surveys. Although this will not predict the future price of these nutrients, it will give us the history of fertilizer prices. After our survey in December I will recreate the graph to show the changes for 2022.

From the graph below you can estimate the potential cost for any of the 3 nutrients. The unit price for Potash was \$6.00 for 2021, so for 60% Potash the quick calculation would be $\$6.00 \times 60 = \$360/\text{ton}$. I have heard of prices reaching double our survey values for December 2021, I hope this is not true but we will see in a few months.



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Fertilizer and Seed Prices, continued

We are also hearing of spiking grass seed prices for 2022, which actually started this year. From what I have read this is due to a number of issues all coming together at the same time. Less acres planted, little carryover, lower yields due to drought, greater demand, and freight costs are all causes of the rising prices. It seems that every commodity is getting hit with some sort of supply issue, hope it gets back to our normal soon.

Stephen McMurtry,
Fertilizer and Seed Program Director

Fall 2021 Corn Survey

Each fall, our inspectors collect new crop corn samples from across the state. All samples are analyzed by our laboratory for nutrient content and a selection are screened for mycotoxins. At this time, we have nutrient content on 33 samples (see below) and the mycotoxin screen has been completed on around 20 samples. To date, we have found no evidence of a mycotoxin issue in our 2021 corn.

Please consider using these nutrient values in your ration software if you are using Kentucky corn.

# Samples	Crude Protein	Crude Fat	Crude Fiber	Moisture
33	6.4%	3.4%	1.3%	15.1%

Dr. Alan Harrison,
Director Feed and Milk Programs

FERTILIZER PRODUCT REGISTRATION FOR 2022 IN KENTUCKY

All Kentucky fertilizer registrations and licenses expire on December 31, 2021 and must be renewed to legally sell fertilizer in the state for 2022. Renewal notices to all current Kentucky registrants/licensees will be mailed or emailed in early November. The renewals list all products registered in the state for 2021, all licenses approved for 2021, 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

Update on the UK Hemp Proficiency Testing Program

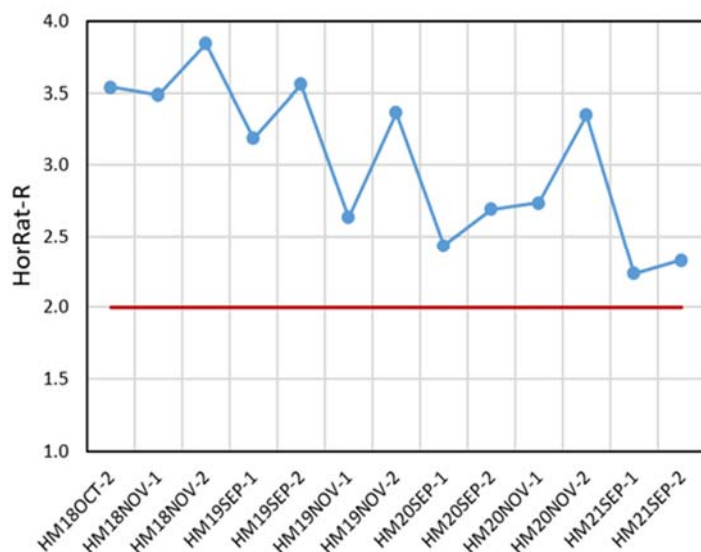
Our Division manages a Proficiency Testing Program for testing Hemp. A Proficiency Testing Program involves one sample being sent out to several different labs. The labs analyze the sample in their lab and send back results that can be collated and compared with all the other labs. The comparison allows labs to evaluate their proficiency in testing for various compounds in hemp.

We began testing hemp for the Kentucky Department of Agriculture in 2017 for compliance to ensure total THC concentration was less than the legal limit of 0.3%. At that time, there was no Proficiency Testing Program for hemp that would help our lab validate our method and ensure we were providing accurate results. The lack of a Proficiency Testing Program also handicapped several labs across the country that were being required to test hemp for legal compliance.

The Hemp Proficiency Testing Program began in our Division in 2018 to fill the void. Four hemp samples are sent out in the fall of each year. There are currently 71 labs in the program. Thirty-seven are public, 31 are private, and 3 are international.

An anticipated result of the program was an improvement in laboratory performance in determining total THC and a decrease in the variability of results from all the labs for a sample. One measurement of variability is the Horwitz Ratio for reproducibility (HorRat-R). The larger the ratio, the greater the variability. The graph on the next page shows the HorRat-R values for each sample have declined over time from 2018 to the current samples in 2021. An acceptable value for HorRat-R is considered to be less than 2 which is shown as the red line. Although the current HorRat-R values are not less than 2, the trend is in the right direction to hopefully achieve those values in the future.

Trend in variability



The program offers many other analytes for testing such as CBD and other cannabinoids, toxic metals, terpenes, and moisture. CBD oil was also offered to labs for testing this fall that contains delta-8 THC which is closely related to delta-9 THC. There is controversy on the legality of delta-8 THC. Some argue it is legal since the Hemp Law only specifies delta-9 THC should be less than 0.3%. However, delta-8 has psychoactive properties similar to delta-9 THC which has supported an argument that it should be illegal. Including delta-8 THC in the Proficiency Testing program will help labs ensure their proficiency in analyzing this compound to prepare for future compliance or service testing.

Dr. Frank Sikora
Director of Laboratories

Inspector Program Update

A decade of changes

I am completing my eleventh year of working for the Division of Regulatory Services. There have been changes within the industry in the last decade. A couple of things I have noticed are the mergers and changes in the fertilizer retail stores and certainly the changes with Cargill and Southern States have

had a major impact in Kentucky. Another big change we are seeing is the inventory of seed kept at retail locations. The inspectors are seeing less seed to sample as many firms have gone to ordering seed as needed instead of placing one big order and stocking up at the beginning of the season. If you have seed left in your warehouse this fall that has a tag where the expiration date will expire before next spring season, it will need to be tested for germination and relabeled before spring.

In the feed business the FDA contracts continue to change as the BSE inspections are now only conducted at firms that use prohibited protein material in the manufacturing of feed at their facility. Since I started a decade ago, we have added the cGMP part 225 medicated inspections at non-licensed feed mills, the cGMP part 507 at all feed mills that manufacture feed of any kind in Kentucky, the VFD inspection was added a few years ago when those VFD drugs used in manufacturing medicated feed were added, and finally last year we started doing the Preventative Control inspections at large firms that require a food safety plan. In the 2020/2021 year we were only able to complete 4 of the PC inspections due to Covid-19. This year we will do a total of 12 Preventative Control inspections at the larger feed mills in Kentucky from November through late winter. We hope to complete these by February before spring seed and fertilizer season starts. If you are a larger firm and have not filed attestation with FDA as a small feed facility, we will be conducting these PC inspections starting this year and will be reviewing your food safety plan during these inspections. Because of Covid-19 continuing to be a concern our inspectors will be calling you in advance as a courtesy before arriving to schedule these inspections.

Our inspectors are continuing to attend trainings to stay up with the current changes in the laws and regulations that affect your business. They are

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available to help you with questions you have and assist you in staying in compliance. The inspectors can review labels for any product you have and help you get new products registered.

2021 corn crop running low on protein

Each fall the inspectors collect new crop corn samples from around the state as they visit farms where corn is being unloaded by farmers. Complete results of this survey to date are presented elsewhere in this newsletter. Of note, with thirty-three samples collected so far, the average protein content is 6.4% (with an average moisture of 15.1%). This could have a significant impact on any feed manufactured using new crop corn. The Division of Regulatory Services has an online feed calculator program that you can use to reformulate your feed for protein [Division of Regulatory Services Feed Program \(uky.edu\)](https://www.uky.edu/divisionofregulatoryservices/feedprogram/). If you are a feed manufacturer and have not had your new crop corn sampled, ask your inspector to collect a sample next time he is in for a visit. We can run the protein level here in the feed lab and get the results back to you quickly to allow you modify your feed formulas if your local new crop is testing lower for protein than in previous years. If you are using corn with a lower protein level, it will lower your protein level in all the feed you manufacture and will cause your violation rate for protein deficiency to significantly increase.

The Division of Regulatory Services has experienced and well trained inspectors to assist you with any questions you may have about seed, feed, and fertilizer. Continue to stay safe and have a wonderful holiday season.

*Jim True
Inspection Program Coordinator*

Upcoming Meetings

We are starting to have some in person meetings again. As of now, all of the following meetings are scheduled to be in person.

Agribusiness Association of Kentucky Agribusiness Summit Holiday Inn Hurstbourne Louisville, Kentucky November 2-4

[KY AgriBusiness Summit — AgriBusiness Association of Kentucky \(kyagribusiness.org\)](https://www.kyagribusiness.org/)

Kentucky Farm Bureau's 102nd Annual Meeting

Galt House
Louisville, Kentucky
December 1-4

American Association of Feed Control Officials 2022 Midyear Meeting

Mobile, Alabama
January 18-20, 2022
[The Association of American Feed Control Officials > Meetings \(aafco.org\)](https://www.aafco.org/)

Association of American Plant Food Control Officials

2022 Winter Annual Meeting/Methods Forum
Mobile, Alabama
February 13-18, 2022
[AAPFCO Meetings](https://www.aapfco.org/)

*We at Regulatory Services hope each of you
have a Happy Thanksgiving, Merry Christmas
and Happy New Year.*



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