

Regulatory Services News

Vol. 63, No. 3

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

Fall 2020

Director's Digest

Anxious for New Year's Eve

I recently read a comment from someone who said they were going to stay up until midnight this coming New Year's Eve, not to wish the New Year in but to make sure that 2020 goes out. Many of us can relate to this statement as we experience Covid fatigue. We are getting tired of social distancing, wearing masks, not going out and here in the south the fear that college football will be cancelled. We've gotten a lot more work done at home but are anxious to go to a ball game, see a movie, eat out, or attend a normal church service or Sunday School class. Our country has suffered through much worse than this pandemic but we will be glad when a vaccine is developed and we can return to "normal."

What will normal look like when this is all over? I recently read an article on pandemic-inspired business trends that will stay when this over and thought it would be interesting to review a few of these and think about how these might relate to your business.

- **Cashless and contactless commerce.** There is

probably nothing more contaminated than money. I've never been one to use a credit card to buy lunch but have during the last three months just so I don't have to handle cash. Many restaurants have even made their stores cash-free to protect both employees and customers. Others have added contact-free pickup and delivery service as well, and many think these options will remain popular.

- **Delivery.** Grocery stores, restaurants, and retailers learned that customers expected more delivery as they worked from home or just wanted to avoid going out during this pandemic. Even industries that hadn't used delivery in the past such as car dealers and bars started offering this service. It is expected that consumers will continue to want more delivery options in the future. I would add that curbside service has become popular as well.
- **E-Commerce acceleration.** Amazon, Wal-Mart and others have used e-commerce for years but

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this business has intensified as people stayed home. On March 12, the beginning of the Covid-19 lockdown, Amazon stock closed at \$1.676.61. By the end of June, it was nearly \$1,000 higher than it was just a few months earlier. As people have become accustomed to online shopping, many may not want to go back to stores when this is over. The growing e-commerce trend also includes local shops moving sales online in order to compensate for lost walk-in traffic and to reach non-local customers.

- **Sanitation.** Clean businesses have always been attractive to consumers, but this pandemic has heightened their concern. Farmers may not object to visiting a dirty, dusty agribusiness with nasty bathrooms but if you want to bring in more urban consumers, then your business had better be clean. I haven't been out in stores much since March but one complaint we are hearing from our inspectors and even others that I work with is that many businesses are no longer allowing customers to use their restrooms. As this trend reverses, customers will be more likely to return if the restrooms are clean and accessible.
- **Shop and source local.** This pandemic has disrupted global supply chains and more people are looking at local suppliers and shops to help them fulfill their needs. When it comes to consumers, people may not want to travel far and instead rely on convenience stores and farmer's markets. When it comes to local businesses sourcing materials, international uncertainty may force a renewed look at local suppliers.

Forbes contributor and University of California, Davis professor Suzy Taherian notes that "companies will be loathe to trust all the supply from one foreign country or even from outside U.S. Companies will look to diversify their suppliers and to favor local suppliers, even at higher

costs."

- **Video Conferencing.** At this time last year, zoom was what I thought cars did at the racetrack but now have participated in more zoom meetings than I can count. While I still prefer face to face meetings, there are conveniences and travel savings offered by using video conferencing. This is a technology that will not go away when this pandemic is over. Video calls and webinars have also been adopted by small businesses as a customer retention tool.
- **Working from home.** This became a necessity here at UK in late March. As in most of your businesses, we have some positions where this is feasible and others where it is not. I have not participated in this myself as my internet service at home is spotty and I have a hard time concentrating on regulatory services work when I look out the window and see things that need to be done on the farm. However, I have discovered we have employees who can work very successfully from home. Many businesses will probably continue to offer this option for some employees when this is over. There will also be a higher expectation that people who are sick do not come into the office, with them either taking sick time or working from home when they are not feeling well.

As with any crisis, there are things we can learn from this one. These are a few of the things that have changed as a result of this pandemic and are likely to continue once it's over. Consumers have developed different expectations of customer service during this crisis. Being able to meet these expectations when this is over may contribute to your business success.

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

Have Seed Packets Appeared in Your Mail Box?

Over the past few weeks I have received notice from other state seed control officials of reports of seed packets being mysteriously shipped within the United States. The packages seem to be originating from China and indicate that the contents may be jewelry, electrical connectors, hair ties, or anything else small in weight. Early indications seem that this is a brushing scam, the shippers create false accounts using a person's name and address and ships items to the address. They will then go online and create fake reviews to give them a higher status with Amazon. This moves them up in rankings of Amazon so when you search a product they are one of the firsts to appear on the page.

Not knowing the kinds of seeds and the potential for introducing noxious plants or disease this is highly alarming. Do not plant or open the packages. Please contact the Division of Regulatory Services or the Kentucky Department of Agriculture if you receive an unsolicited package of seed. Below is a message from Commissioner Quarles produced July 27th about the issue. I have also included additional links on the topic.

<https://www.kyagr.com/ky-agnews/press-releases/2020/Agriculture-Commissioner-Ryan-Quarles-sounds-alarm-unsolicited-foreign-seeds.html>

<https://www.fox13now.com/news/local-news/utah-department-of-agriculture-investigates-mysterious-seeds-sent-from-china-to-tooele>

<https://www.forbes.com/sites/wadeshepard/2019/10/25/americans-are-still-receiving-unordered-packages-from-asian-e-criminals/#4e351ca969f3>

<https://www.bbb.org/article/news-releases/20509-amazon-brushing-scram-indicates-a-serious-problem-for-victims>

***Steve McMurry,
Director of Fertilizer and Seed Programs***

A Brief History of AAFCO and the Division of Regulatory Services

The Association of American Feed Control Officials (AAFCO) was conceived in 1909 to help standardize feed laws and regulations across the United States. AAFCO is a non-profit association comprised of federal officials and state feed control officials from across the US, Costa Rica, Puerto Rico and Canada. AAFCO members strive to provide consumer protection, safeguard the health of man and animals and provide a structure for orderly commerce for the animal feed industry.

Dr. J. D. Turner represented Kentucky at the very first meeting in Chicago of the fledgling organization, then called the 'Association of Feed Control Officials.' He was one of eight control officials that helped to pave the way for the current AAFCO structure and prominence and went on to serve as the 5th president of the organization in 1913. Division of Regulatory Services personnel have gone on to hold the AAFCO presidency with Dr. Bruce Poundstone in 1950, Dr. Eli Miller in 1986, and myself this year for 2020.

Over the past 110 years, countless other Kentuckians and members of the Division of Regulatory Services have served on committees, chaired committees, provided scientific expertise, hosted seminars and meetings, and generally participated in AAFCO at every level. All of this work has been essential to ensure consumers are getting what they pay for, animal health is protected, and there is a level playing field for industry. Our Division currently has personnel that serve as AAFCO ingredient investigators, committee chairs, committee members and on the board of directors.

The Division of Regulatory Services believes that in playing a leading role in AAFCO, we are helping secure the safety of animal feed as well as provide a level playing field for the associated industry. Standardizing regulations, labeling requirements, and inspection processes across the 50 states means that firms aren't being regulated 50 different ways. Consumers can be confident that animal feed

purchased from a Kentucky firm versus an out-of-state firm has been produced under similar regulatory scrutiny. The Division will continue to be a leader to ensure that Kentucky firms, livestock and pets, and consumers continue to benefit from a consistent regulatory framework.

Free this Week! Virtual 2020 AAFCO Annual Meeting August 5-7

Starting this Wednesday, the Association of American Feed Control Officials (AAFCO) biannual meeting will be held virtually for the first time and anyone can listen in for free. Visit <https://www.aaeco.org/Meetings/Annual/2020> to access the schedule, committee agendas, and phone-in instructions. If you are interested in learning about emerging animal feed ingredients, new developments in pet food regulations like ‘human grade’ claims or emerging laboratory trends and methods for animal feed be sure to take advantage of this opportunity. In addition, state regulatory agencies will be voting on new animal feed ingredient definitions and regulations and the schedule includes two speakers that will address the current pandemic. On Wednesday, Dr. Bernadette Dunham will be presenting ‘An Introduction to One Health and its Role in the COVID-19 Pandemic,’ while on Thursday, Dr. Timothy Schell of the Director of the Office of Surveillance and Compliance with the FDA Center for Veterinary Medicine will be discussing ‘Coronavirus Impacts on Animal Food.’

*Kristen Green,
Registration Specialist*

Fertilizer and Seed Program Regulation Changes Have Been Submitted

Fertilizer and seed regulation changes were submitted in June to the Legislative Research Commission. Written comments can be submitted until August 31, 2020. We have a hearing scheduled for the fertilizer changes on August 27th and the seed

hearing scheduled for August 28th. These will be cancelled if we have not heard of anyone attending 5 days ahead of the scheduled meeting. Below are the highlights of the changes.

Fertilizer changes:

- ♦ Created a new regulation for licenses and product registration
- ♦ Plant nutrient guarantees and labeling were brought into one regulation
- ♦ Definitions were removed and are now incorporated by reference to the AAPFCO OP 2020
- ♦ How to guarantee non-plant food ingredients and beneficial substances were defined

Seed changes:

- ♦ Update to the 2019 AOSA Rules for Testing Seed
- ♦ Tall fescue endophyte testing fee increased \$10
- ♦ KY Seed Certification standards updated to the 2020 Handbook

*Steve McMurry,
Director of Fertilizer and Seed Programs*

Protein Concentrations in Kentucky Feed Ingredients

In past articles, I have reviewed feed sampling results and compliance with meeting label requirements. The focus of past reviews have been livestock feed and pet food but this review will look more closely at one nutrient – crude protein – and the common ingredients that are used in livestock feed manufacturing in the state.

The data used in this review combines 3 years of sampling data from 2017 through 2019. Our inspectors sample a wide variety of commodity ingredients but this review will include only the most commonly sampled: corn, corn gluten feed, distillers dried grains, soy hulls, and soybean meal.

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Protein concentrations, continued

In 2019, our inspectors collected samples of 1,086 livestock feeds. Of these samples, 13.9% failed to meet the minimum crude protein guarantee on their label, making protein the most likely nutrient to be deficient. By our regulations, crude protein concentration must be no less than 3% below the label guarantee. For example, a beef feed guaranteed at 14% crude protein must contain at least 13.58% protein to comply with our regulations. When products fail to meet their protein guarantee, one area to review is the crude protein concentrations of ingredients used in the formulation. If the formulation program has values for crude protein that are considerably higher than the crude protein of the actual ingredients used, then protein will be lower in the mix than intended. An understanding of the average values and range of protein in locally available ingredients is required.

The table shows total samples analyzed, average and range of crude protein, and percentage of samples with guarantees that failed to meet those guarantees. The graphs show the distribution of samples in five protein ranges for each ingredient.

Corn average crude protein was 6.9%. The distribution graph shows that 55% of samples were between 6 and 7% protein with another 40% between 7 and 8%. Of the five ingredients, the highest percentage of samples not meeting protein guarantees was corn. Whole shell corn is not required to carry a protein guarantee but ground, cracked, or rolled corn does need a label that includes a minimum crude protein. Approximately one third of our samples had guaran-

tees and they ranged from 5 to 8% minimum. Every sample with a guarantee of 6.5% or less met the minimum crude protein. For formulation purposes, I would recommend a crude protein level of 7%.

Corn gluten feed samples averaged 20.1% crude protein. Corn gluten feed is typically guaranteed at 17 or 18% crude protein, a value below our 3-year average.

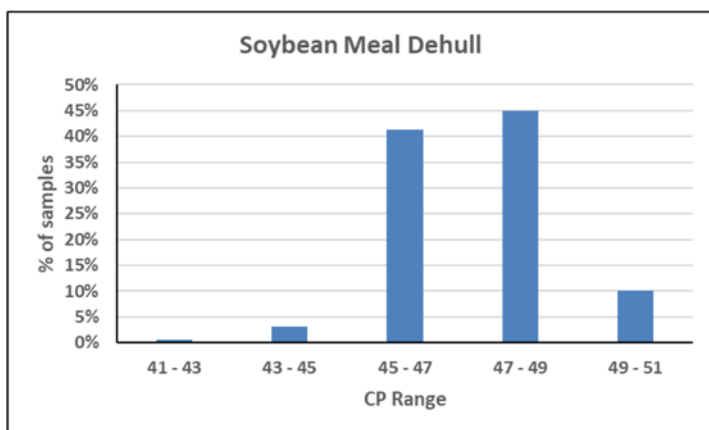
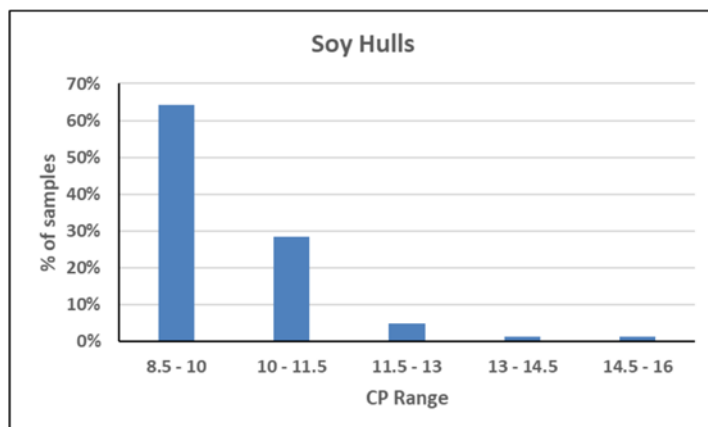
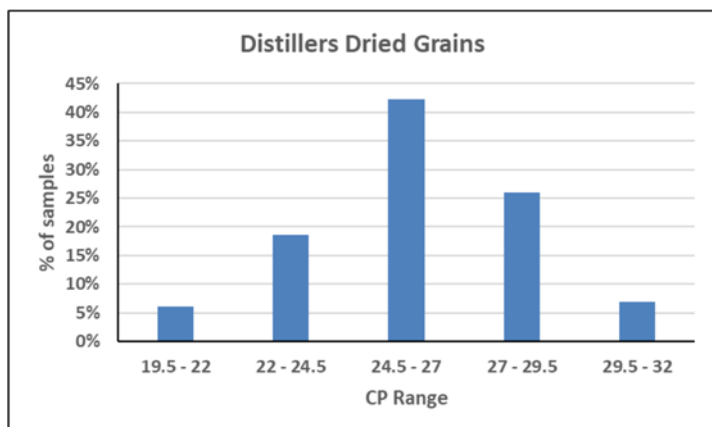
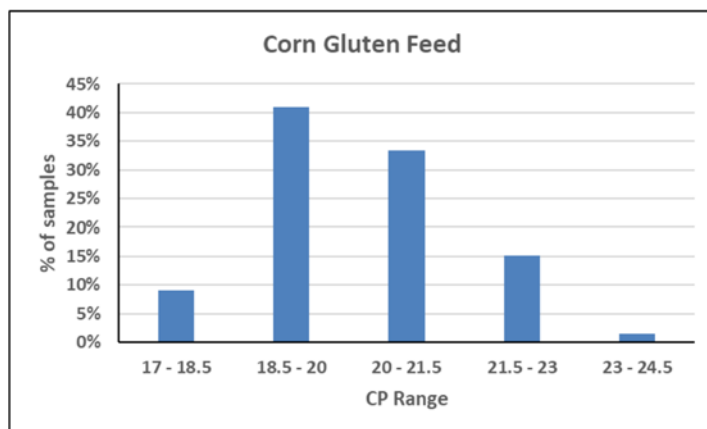
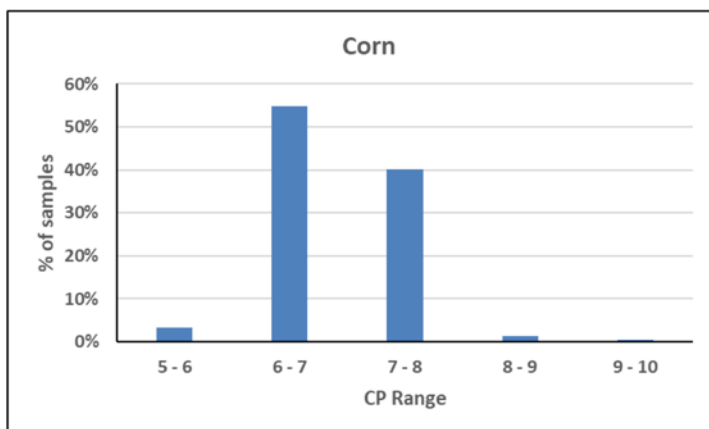
Distillers dried grains averaged 26.1% crude protein. The range of protein is around 20 to nearly 31% and that is not surprising with these samples. The 215 samples include products identified as coming from fuel ethanol plants, products from beverage distilleries, and products not identified by source. Average protein for the DDG from ethanol plants is around 28% while slightly under 25% for DDG from beverage plants. Most beverage distilleries guarantee their product at 25% and this is a reasonable value for a formulation program. If the DDG is from an ethanol plant, 27-28% protein could be used in formulation.

Soy hulls averaged 9.9% crude protein. With our soy hulls samples, 68% were between 8.5 and 10% crude protein. Most soy hulls guarantors are labeling their products at 9% minimum crude protein and this value works well in formulation.

Dehulled soybean meal samples averaged 47.2% crude protein. The range of 45 to 49% crude protein covered 86% of our samples. Soybean meal guarantees are usually 47, 47.5, or 48% crude protein. A formulation value of 47% would be recommended.

UKDRS Commodity Samples 2016-2019

	Total # Samp	Crude Average (as-fed)	Min	Max	% Fail
Corn	401	6.91	5.32	9.75	25.6%
Corn Gluten Feed	66	20.12	17.18	24.07	1.5%
Distillers Dried Grains	215	26.07	19.96	30.85	13.7%
Soybean Hulls	81	9.94	8.54	14.63	4.9%
Soybean Meal Dehull	320	47.23	41.02	50.26	7.5%



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

Risks and Opportunities, ISO/IEC 17025:2017

One of the updates to the updated ISO 17025 Standard is Section 8.5, “Actions to address risks and opportunities”. This is a strongly emphasized “risk based” thinking and the word “risk” appears over thirty times in the 2017 standard. However, the previous ISO 17025 Standard approached improvements by referring to “preventative actions” and only refers to the word “risk” four times!

Let’s think about how we address risk in everyday life, i.e. not in a laboratory. We take driving for granted most of the time. We take for granted that we will arrive at our destination unharmed and intact. But we (or we **should**) mitigate our risk by staying off of our cell phones, following the speed limit, following the rules of the state, city, or county we are in, have gas in our tank, use our blinkers, and

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have maintenance performed on our vehicles regularly. All of these steps are various ways we reduce our risk of not arriving at our destination unharmed and intact. Another example of risk reduction is when we prepare our food. We keep our surfaces clean, cook our meat to certain temperature to kill any lingering bacteria, rinse our vegetables and fruits prior to eating, and use clean utensils. Those are easy routine areas that we have adopted in our day to day life to reduce harmful risks. What about a non-routine task? If you are going to change a lightbulb in a ceiling fan, you will make sure the fan is off to reduce risk of catching your hand, or if you are tall your head, in the fan. Typically, you will use a step-stool or small sturdy ladder—not a rocking chair! This same thinking process can be applied to a laboratory's quality management system.

In order to address risks and opportunities, you have to know what the risk is, or what makes achieving the objective uncertain. Once you have decided what risks are possible to your objective, you have to decide what the level of risk is. You have to figure a way to express the importance of the risk taking into account the consequences and the probability of it occurring. The next step would be to evaluate the risk. The level of risk is compared to the acceptable criterion. To think about this using driving as an example, you are about to take a trip to the doctor office which is an hour away. However, you know you will be sitting idle at stoplights because of driving during rush hour. You check your gas level and it's between $\frac{1}{2}$ and $\frac{1}{4}$ tank full. If you don't stop and get gas before you go, you could run out of gas if there is a bad accident on the highway, which would increase your idle time in your vehicle; there may be an unexpected detour due to unscheduled utility work which would increase your distance and/or time in the vehicle; you could get behind a tractor on the way on a two lane road with no legal passing; or other unexpected time/distance delays. So, when evaluating whether or not you should fill up your tank, you compare the risk (running out of gas), the level of risk (the likelihood you would run out of gas) and perform your risk evaluation (compare the probability of running out of gas before you get there or before you get home). The risk treatment is optional ways you may avoid taking the risk at all (either by filling up your tank before you get on the highway or on your way home, depending on your gas mileage). The risk treatment may have more than one or two opportunities. It boils down to what is your best option to make it most probable that whatever choice you make, you will not run out of gas on your way to and from your doctor visit. Of course as a laboratory, we want to minimize the risk of

errors by reducing our residual risk (the risk after you've performed your risk treatment) and increase our opportunities, which in the lab's point of view is an event with potential positive outcome for UKDRS.

This risk-based thinking enables the reduction in prescriptive requirements and replaces them with performance requirements. This will allow laboratories to use extra flexibility in risk reduction. However, it's not only specifically intended for laboratory tests. According to ISO/IEC 17025:2017 Section 8.5.1 it's to assure that the quality management system in place is effective; it's to enhance the opportunities to achieve the purpose and objectives of the laboratories; it's to prevent or reduce any undesired impacts and the potential failures in the laboratory activities; and to achieve improvement. In ISO/IEC 17025:2017 Section 8.5.2, the lab is to plan the actions to take to address any identified risks and take the opportunities to improve performance of the lab. The laboratory is also to plan how to integrate and implement the actions into its management system and how to evaluate the effectiveness of the actions. A discussion of all the places in the management system risks are to be addressed include the following sections of ISO 17025: 4.1.4 impartiality of activities, relationships; 7.8.6.1 statements of conformity, unless proscribed by customer; 7.10.1 non-conforming work; 8.7.1 corrective actions; and 8.9.2 the results of identifications are to be discussed in the management review process.

The laboratory's first step is to identify the potential risks by considering both internal context of the organization and its external context. This means the laboratory not only consider the risks related to the customer (our Regulatory Programs) but also to whom receives the information the laboratory generates for our customers. Risk identification methods may range from something such as common sense and brainstorming, the use of pre-established lists for a professional sector, and the use of standards setting good practices. The risks can address: what can happen and why; what are the consequences; what is the probability of their future occurrence; and factors that will reduce the consequence of the risk or the probability of risk. One of the most important things that we have discussed in previous quality articles: DOCUMENT! If you don't have a record of the action, it didn't happen! Remember, the purpose of the ISO 17025 standard is to make sure that "you do what you say and say what you do", with "say" actually meaning "write" and/or "document"!

Another important discussion point is to address risks and opportunities proportionally to the potential impact on the validity of the laboratory results. This is stat-

ed in ISO/IEC 17025:2017 Section 8.5.3. Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. Not all opportunities have a negative impact on laboratory activities. Opportunities can lead to expanding the scope of laboratory activities, addressing customer requests, using new technology, and other possibilities. Some discussion points seem pretty intuitive but others may seem a bit daunting. There are a number of tools in our tool bag that we can use. In fact, there are so many different tools that ISO devoted 2 standards to risk! ISO Standard 31000:2009 Risk management—principles and guidelines and ISO 31010:2009 Risk Management—risk assessment techniques are both devoted to identifying, evaluating, and mitigating risk. Discussing all of the available resources will have to be a different article.

So to sum all of this up, ISO 17025:2017 states in its introduction that it requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative

effects. This is something that the laboratory is supposed to be doing all throughout the year, not just during the auditing and management review processes. The laboratory is to record objective evidence for compliance with the risks and opportunities demonstrating that the organization has adopted a risk based approach.

In conclusion, we at Regulatory Services, take pride in the services we provide to our customers, consumers, producers, and manufacturers. We are continuously trying to improve the services we provide by addressing our risks and any opportunities. By working with our Regulatory Programs we can provide high quality service to all stakeholders involved. We are planning to be assessed for accreditation to the ISO/IEC 17025:2017 at the end of August. This has been a long journey that is not over. We all have worked very hard to reach this goal and I am proud of each and every contributor to this upcoming achievement.

***Dr. Sharon F. Webb,
Director, Quality Program***

Personnel Notes



Tina Tillery retires

If you've communicated with the Regulatory Services Seed Laboratory in the past 42 years, chances are you've visited with Tina Tillery. Tina started to work at Regulatory Services on June 5, 1978. She will retire on August 28, 2020.

Tina started out as an analyst in the germination lab for 3 years, then moved to the purity lab. She became the Seed Lab Supervisor in 1987.

Reflecting on her time here, Tina says: "I do want to say that for the most part, it's been a great experience working for Regulatory Services. I made many friends in the state's seed industry and am going to miss conversing with them and with my coworkers. I do know that I'm leaving behind experienced analysts in the seed lab and that they can handle whatever comes up in the future."

As for retirement, the current pandemic has curtailed any travel plans. Tina recently moved to Berea and plans on many home improvement and yard chores. She also looks forward to spending more time with her dog and may even look for another one.

Many thanks to Tina for her 42 years of service to the seed industry in Kentucky and we wish you well in your retirement.

Regulatory Services News is published by:

Division of Regulatory Services
College of Agriculture, Food and Environment
University of Kentucky
103 Regulatory Services Building
Lexington, KY 40546-0275

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