Regulatory Services News

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Director's Digest

Most of us as scientists can relate to Mr. Spock from Star Trek and think that most issues can be resolved with logic. We look to science for answers on Genetically Modified Organisms (GMO's), global warming, antibiotic resistance, etc. Unfortunately, there is a lot of "junk science" out there to prove almost any point and the majority of people can't distinguish "junk science" from real science. In addition, the myriad of news networks are competing for viewers and will quickly report on any controversial study as soon as it comes out without checking to see if the research is sound. Add social media to the mix and before long you have many people convinced that agriculture is all run by big business and pumping our food full of toxic chemicals. There are thousands of sound scientific studies and meta-analyses that show the safety of GMO's. Eighty nine percent of American scientists affirm that GMO's are safe to eat but with all the negative coverage on TV and in social media, only 37 percent of Americans believe GMO's are safe.

Junk science is defined as "faulty scientific information or research, especially when used to advance special interests." The analogy I like is that of the Texas sharpshooter who goes out and shoots holes in the side of a barn. He then goes back and paints targets around the holes to show what a great shooter he is. There are many good websites that will debunk junk science but most people never bother to research whether or not what they see on TV or Facebook is the result of good science.

What do we as members of the agricultural community do to educate consumers about the safety of food? We are going to run into people at parties, sporting events or airports that find out we work in agriculture and will have questions or opinions on food safety. Depending on their attitude it is easy to become defensive but if we can't convince them of food safety, we certainly don't want to send them away convinced that we are the problem. One of the first things to do is determine if they are willing to discuss or only give you their opinion. If you determine they are unwilling to have a reasonable discussion, kindly acknowledge they are certainly entitled to their opinion and you would be happy to discuss but not argue. Be willing to graciously dismiss yourself if all they want to do is argue. "Give up trying to make me give up" is a quote by Masashi Kishimoto appropriate to this situation.

If you find someone who is sincerely interested in having a conversation about food safety or other

(continued on page 3)

What's inside. . .

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agricultural topics, then the Center for Food Integrity (CFI) offers the following suggestions:

How to Engage:

Be committed to having a conversation, not just educating, defending or correcting misinformation.

Be principle-driven: Know your values and how values drive you when it comes to agriculture/food.

Keep your emotions in check: Conversations are important, but they may get uncomfortable.

With that approach in mind:

Listen – Actively listen, without judgement, for agreement and points of connection to understand how their concern is tied to their underlying values.

Ask – Ask questions to invite dialogue and clarify their perspective.

Acknowledge: Show that you heard the question or statement.

Understand: Ask questions that show you're working to understand them better.

After listening and asking questions, engage and share:

I welcome increased interest in food today. So much has changed over the last half century it is understandable that new technology is being met with skepticism. Consumers and their families deserve the safest and healthiest products in the world. I/we appreciate hearing concerns and answering questions. Our goal is for consumers to share our confidence in the safety of our products and the ethics behind our practices.

Global estimates point to the need for 100 percent more food by mid-century than what is being produced today. To meet the growing global demand for food, we must produce more using less through innovation and the responsible use of technology, which America's farmers have been doing for decades. It is in humanity's best interest to use technology in food production because it allows us to have the safest, most affordable and nutritious supply of food needed to feed a rapidly growing global population.

Consumers today understandably have difficulty identifying with today's food producers. Over the last half-century, agriculture has changed in the same manner as other sectors. Mobile phones have changed the way we communicate. Online services have changed the way we shop, bank, and entertain ourselves. Most people appreciate the convenience and efficiency that new technology affords us. Agriculture has progressed similarly, but those advances aren't always recognized because so few people are involved in farming.

These suggestions from CFI on how to engage with consumers go against our normal inclinations to use logic and express our skepticism over much of the junk science they espouse. We see where a deficiency of Vitamin A causes up to 670,000 deaths per year in children under the age of 5 and therefore see the benefits of products like Golden Rice which has been genetically modified to provide much needed beta carotene and can prevent these deaths. It infuriates us when people and governments won't utilize this technology because they are afraid of "Frankenfood". Our tendency is to argue the benefits and logic of Golden Rice without discussing the emotions and values behind the consumer's fear of it. We can't afford to win the argument but lose their trust.

We owe it to our industry to promote what we do whenever we get the chance. The trick is to remember that the goal is to have a discussion and not a debate.

Dr. Darrell Johnson,
Executive Director

Registering Pet Treats in Kentucky

The Division of Regulatory Services (Division) routinely receives calls from Kentucky citizens wanting to start their own businesses producing pet treats in their kitchens. In this article, I hope to simplify the registration process for these new business owners.

All commercial animal feeds (this includes pet treats and pet foods) must be registered with the Division prior to sale in the state of Kentucky. To register, a firm must submit a registration packet which includes:

- **A completed application form**. This form can be found on our website at: http://www.rs.uky.edu/regulatory/feed/pet_treats/
- **A copy of each product label**. This can be an actual label or a legible copy.
- **Payment**. Submit $50.00 for each product sold *exclusively* in 10 pound packages or less *OR* for products sold in package weights above 10 pounds submit no payment at this time as a quarterly tonnage form will be provided to your firm.

Once the complete packet has been received by the Division, the Registration Specialist will review the labeling for compliance with Kentucky Feed Law and Regulations available at: http://www.rs.uky.edu/regulatory/feed/feed_laws/. We strongly encourage new Kentucky companies to submit a copy of labels for review prior to printing expensive labeling as there are often changes required after review.

You can find information about the basic elements required on pet treat labeling on our website. For simple treat formulas, our office may be able to assist you with the required guarantees. The Association of American Feed Control Officials has developed two websites, http://petfood.aafco.org/ and http://talkspetfood.aafco.org/, which are also excellent resources for both consumers and new pet food businesses.

After the Division has completed a label review, you will be notified by mail or email if your registration has been accepted. If there are changes or additional information required, the Division will provide your firm with guidance about what must be done or provided to bring your labels into compliance.

Since regulation of pet foods is handled on a state by state basis, a successful product registration in Kentucky ONLY allows you to sell your product in Kentucky. If you wish to sell your product(s) in another state, you must comply with that state's laws and regulations.

Once your firm has completed the registration process and all products are accepted for registration, you may sell your products in Kentucky. Please note that for small package products (those sold exclusively in 10 pound packages or less) annual renewal is required. Our registration year runs on a fiscal year basis from July 1 to June 30th. The Division will automatically send your firm a renewal application with renewal instructions in June for the upcoming fiscal year.

Still have questions? Please contact our Registration Specialist Kristen Green at Kristen.mary.green@uky.edu or 859-257-4496.

Kristen Green,
Registration Speicalist

Standard Operating Procedures---What are they and why do they matter?

To continue our discussion about moving towards ISO 17025:2005 accreditation, I am introducing what Standard Operating Procedures (SOPs) are and their importance in a regulatory setting. An important aspect of a quality system is to work according to an unambiguous SOP. The whole process from taking the official regulatory sample to the sending out of the analytical result should be described by a continuous series of SOPs. We can define a SOP as a document which describes

the regularly recurring operations relevant to the quality of the process. The purpose of a SOP is to carry out the operations correctly and always in the same manner.

A SOP is a compulsory instruction. If any deviations from the instructions are allowed, the conditions for these should be documented including who can give permission for this and what exactly those deviations will be. The original should be in a secure location but working copies should be authenticated with stamps and/or signatures of authorized persons.

There are a number of categories and/or types of SOPs. In some situations, the name "SOP" may not be appropriate and may be designated as protocols, work instructions, or simply registration forms. Also, any worksheets, e.g. spreadsheets, log in sheets, chain of custody sheets, to any procedure have to be standardized too.

Typically, the first SOP developed is how to make SOPs in other categories such as: methods to describe how to test for something; or safety procedures/protocols; or operating specific instruments, apparatus, or other equipment; preparing calibration standards or reagents; receiving of samples; Quality Assurance; archiving and how to deal with complaints.

Initiating a SOP should include a procedure for preparing, implementing, and management of the documents. It should establish and record who is responsible for the proper distribution of the documents, the filing and administration (e.g. of the original and further copies). It should also be indicated how frequently a valid SOP should be evaluated and who will do that. This "SOP" of a SOP should include elements such as who can or should make a specific type of SOP (e.g. sample receiving, a specific method, or administrative SOPs), who approves the proposed SOP, who approves the SOP procedure, who decides upon the timeline of the implementation process, how revisions are made or how a SOP is withdrawn from use.

ISO 17025:2005 does require certain procedures defined using a SOP and require all SOPs to have certain basic elements. ISO 17025:2001 tells you WHAT you have to do. However, it does not tell you HOW to do something. SOPs are supposed to be dynamic, living documents that support continuous quality improvement. It requires standardized formatting, standardized outline structure, a standard template. The document control elements are required for each SOP which will provide a unique identity, the date of original issue, identification of the revision, page numbers, total number of pages, and authority issuing the SOP.

The first page of the SOP should mention pertinent information so the reader will know the title of the SOP, a summary of the contents including the purpose, scope, and principle, any related SOPs used in the current SOP, possible safety instructions, name and signature of the author and the date of the signing, and the name and signature of authorizing person with the date of their signature. The SOP should also include any necessary equipment and reagents (including grade). It should be written in a clear unambiguous imperative description in a language mastered by the user. It's recommended to include criteria for the control of the described system during operation. If the SOP is particularly lengthy, then it is recommended to include a list of contents, and always include any references. When writing the SOP always remember your audience. Is the SOP intended for any person picking up the document to follow how to turn in a leave request? Or is the SOP intended for a person trained in a specific technical area analyzing for something specific in a fertilizer?

SOPs should clearly outline responsibilities of various functions in the laboratory. For example, who performs equipment maintenance? Is one person responsible for performing weekly maintenance of all balances or does each person perform weekly maintenance of the balance they use daily? Who is going to make sure that all the weekly maintenances are performed on all the balances? Who reviews the data? Does one person review all the data generated in the laboratory or does each supervisor review certain data? Who assigns root cause analysis? Who performs management

SOP's, continued

review? Who performs vendor reviews? All of these questions (and more) must be clearly outlined so that everyone understands.

All SOPs are subject to the Quality Management System (QMS) and all protocols and SOPs, including the administrative SOPs, should be kept as simple as possible, especially in the beginning. The QMS should grow by trial and error. In the beginning, most attention will probably be focused on basic operational SOPs and as time goes by the attention will shift to record keeping and filling gaps as practice reveals missing links in the links to Quality Assurance. Perhaps the most important part of an SOP is that your SOP is written EXACTLY how the procedure is performed.

The SOP will begin as a new SOP, and then be revised as necessary. Once revisions are made, previous versions of the SOP will be archived and maintained. References for revised SOPs will include previous versions of the SOP. An SOP may live a long life with multiple revisions and numbering as improvements are made to the method and/or QMS. It is important to have a publication management strategy and a clearly defined review and archive schedule.

Moving towards ISO 17025:2005 accreditation and implementing more strenuous quality guidelines will increase the defensibility of our data and the safety of the food and feed in the Commonwealth. This will allow for standardization of laboratory competencies and validity of laboratory results across the nation. This is a time-consuming process that will be well-worth all the changes and improvements to our laboratory procedures.

Dr. Sharon Webb,
Director of Quality Control

Preparing for the New Veterinary Feed Directive Rules

On January 1, 2017, the new veterinary feed directive rules on antibiotics in animal feed and water will take effect. This is the culmination of the Food and Drug Administration (FDA) 3-year plan that will radically change the use of antibiotics in food animals. The plan focuses only on those antibiotics used in both human and animals and addresses the issue of antimicrobial resistance while keeping these drugs available to the feed industry.

The antibiotic drugs used in the feed and water of food producing animals affected by the new regulations **include** apramycin, chlortetracycline, erythromycin, hygromycin B, lincomycin, neomycin, oleandomycin, ormetoprim, oxytetracycline, penicillin, streptomycin, sulfadimethoxine, sulfamerazine, sulfamethazine, sulfaquinoxalene, tylosin, and virginiamycin. Drugs **not included** include ionophores (monensin and lasalocid), decoquinate, amprolium, carbadox, bacitracin, and flavomycin. These drugs are not used in human medicine. The bottom line on the new regulations is that antibiotics will still be available in feed (or water) for treatment, control and prevention of diseases. However, these 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.

Examples of current feed products that will be affected by the new regulations

Many firms in Kentucky sell a preconditioning feed with a combination of chlortetracycline and sulfamethazine ("AS 700") used to keep animals on feed after shipping. This product will not change but the label will. The most common medicated milk replacer contains both neomycin and oxytetracycline. Again, this medicated milk replacer would still be available but could not be sold to the producer without a valid VFD. Another common beef product is mineral or supplement with chlortetracycline labeled for increased weight gain, improved feed efficiency, and reduction of liver abscesses. After January 1, this product would require a VFD but would also require a new label without the weight gain and feed efficiency claims. After the regulations take effect, a swine finisher with a chlortetracycline level labeled for increased weight gain and improved efficiency could no longer be legally sold. Veterinarians would not be allowed to write an extra-label prescription for an antibiotic on the VFD list with an

Prepare for VFD, continued
indication for use of growth promotion.

Preparing for the coming regulation changes
As the agency responsible for feed regulation in the state of Kentucky, the feed program of the Division of Regulatory Services has been focusing on educating stakeholders about the changes taking effect in January. Our inspectors have had many conversations with feed manufacturers, feed distributors, and producers. We have worked with extension specialists and veterinarians and distributed posters for display in feed mills that have sparked conversations between producers and feed dealers.

Over the next few months, FDA is working on the transition to the new regulations. They have requested that drug sponsors notify their customers and begin to use transitional labels on products switching to VFD status. They have also encouraged drug sponsors to manage their inventory to ensure proper labeling after the first of the year.

All feed distributors of products under VFD status must file a one-time notification with FDA of their intention to distribute VFD feeds. In addition to the distributor notification form, manufacturers of VFD feeds must also have on file an acknowledgement letter from their distributor customers. Basically, this letter or form states that the purchaser of the product understands the rules regarding distribution of feeds under VFD status. Both the distributor notification form and acknowledgement letter are available on our website.

For the producer, it is critical that you have a relationship with a veterinarian that knows your animals and operation and is familiar with the VFD regulations. If your operation does not have a regular veterinarian or clinic, I would highly encourage you to find one in your area.

Final thoughts
We are not losing the option of using antibiotics in animal feed and water, but the rules are changing. Many of the antibiotics commonly in use in animal feed will now require the involvement of a veterinarian and more paperwork for everyone. Producers may want to consider alternatives that do not involve VFD paperwork, particularly ionophores (monensin and lasalocid) and probiotic supplements. There is the potential for some reduction in product availability if some distributors decide not to carry products that require a VFD. However, I'm confident that we will all learn how to deal with this new reality.

For more on the new VFD regulations
VFD Central: http://feedstuffs.com/vfd.aspx
University of Kentucky Regulatory Services: http:www.rs.uky.edu

Dr. Alan Harrison,
Director of Feed and Milk Programs

Pet Owners In The Know - What's In A Name?

Did you know that the name of your dog or cat's food can actually tell you quite a bit about what is in that food? Standardized naming requirements developed by the Association for American Feed Control Officials (AAFCO) and incorporated into many state laws, including into Kentucky law and regulations, outlines how specific ingredients can appear in a product name for a pet food. The product naming rules may not be intuitive, but they can provide the informed consumers with valuable information.

Let us consider four similar product names and what they tell us:

Woofie's Beef Dog Food is comprised of at least 95% beef. This is generally referred to as the "95% Rule" which requires that a named ingredient listed in a product name without a descriptor must comprise 95% of the weight of the product. The 95% Rule does allow water added for processing (seen often in canned foods) to be excluded from the calculation so long as the added water is not more than 25% of the total product weight.

Woofie's Beef Dinner Dog Food has the descriptor word 'dinner' in the product name. This product would fall under the "25% Rule". This rule requires that the named ingredient must comprise at least 25% of the product weight and that the name must include an appropriate descriptor. Other common and acceptable descriptors include 'entrée', 'platter', 'formula' and 'recipe'.

What's in a name?, continued

Woofie's Dog Food with Beef falls under the 3% or "With Rule". In this case, the named ingredient beef must be at least 3% of the formula.

Woofie's Beef Flavor Dog Food does not necessarily contain beef. In this case, the pet food must contain a natural or artificial source of beef flavor.

While there are certain limited exceptions to these rules, having a basic understanding of pet naming rules can give the informed person a quick way to understand what is in your furry friend's food.

Kristen Green,
Registration Speicalist

Proposed Seed Regulation Changes due to Seed Law Changes

During the 2016 Legislative Session some needed additions and updates to the Kentucky Seed Law were passed by both houses and will became effective on July 15, 2016. Due to the changes in the Seed Law, the Division will be proposing the following regulation changes.

- The "Rules for Testing Seeds" issued by the Association of Official Seed Analysts will be updated from the 2012 version to the 2015 version.
- We are proposing to start Semi-Annual tonnage reporting for seed in 2017. The reporting periods would be January thru June and July thru December.
- Due to the increase in consumables for the seed lab, the following increases are being proposed.
    - ◊ Samples of coated or treated seed which have to be hand washed will increase from ten dollars ($10.00) to fifteen dollars ($15.00).
    - ◊ Tall Fescue Endophyte testing will be increased from one hundred dollars ($100.00) to one hundred fifteen dollars ($115.00).
    - ◊ Biotechnology trait identification will be increased from twenty five ($25.00) to thirty dollars ($30.00).
- Clarification on the one (1) free test per year will be specified as a complete test which includes purity, noxious weed seed examination for KY, and a germination test or the equivalent cost to a complete test. Additional items will be charged accordingly.

Stephen McMurry,
Director of Fertilizer and Seed Programs

Fertilizer Stop Sale Release and Penalty Payments

Over the 2015 fall and 2016 spring fertilizer seasons, the Division of Regulatory Services sampled over 2,700 products for analysis. Of those samples, less than 8% experienced one or more deficiencies.

For those samples which experienced a deficiency, I am enclosing some helpful hints in getting those stop sales and penalty payments resolved. The top of the stop sale notice describes the grade, form, amount, and brand of the fertilizer under stop sale to help identify which lot being offered for sale is under a stop sale notice. On the next page is the bottom portion of a stop sale which needs to be completed and sent to the Fertilizer Program for release.

When a stop sale is received the seller is notified not to sell, offer for sale, remove or permit removal from the premises the fertilizer until released by the Division of Regulatory Services. On the left hand side you will need to reconcile how much fertilizer is still on hand at the point the stop sale was received. Please identify how much fertilizer is on hand, sold to an identifiable purchaser, and sold to an unidentifiable purchaser. These three items when added together will give you the total tons which should equal the amount sampled in the stop sale notice.

The actions you may take to request a release include the following located on the right side of the stop sale notice:

- Return to manufacturer for reprocessing
- Relabel – with an appropriate price adjustment
- Penalty payment to the University of Kentucky
- Penalty payment to the consumer, a receipt of payment should be sent to the Division
- Or a combination of the above actions

When the stop sale was received, the disposition of this lot of fertilizer was:	Actions you may take: Check Appropriate Actions
_____ Amount on hand (Tons/Packages)	_____ Return to Manufacturer for reprocessing
_____ Amount sold to identifiable purchaser	_____ Re-label – Price Adjustment
_____ Amount sold to unidentifiable purchaser	_____ Penalty payment to University of Kentucky Regulatory Services
_____ Amount Total	_____ Penalty payment to consumer. Send receipt by:

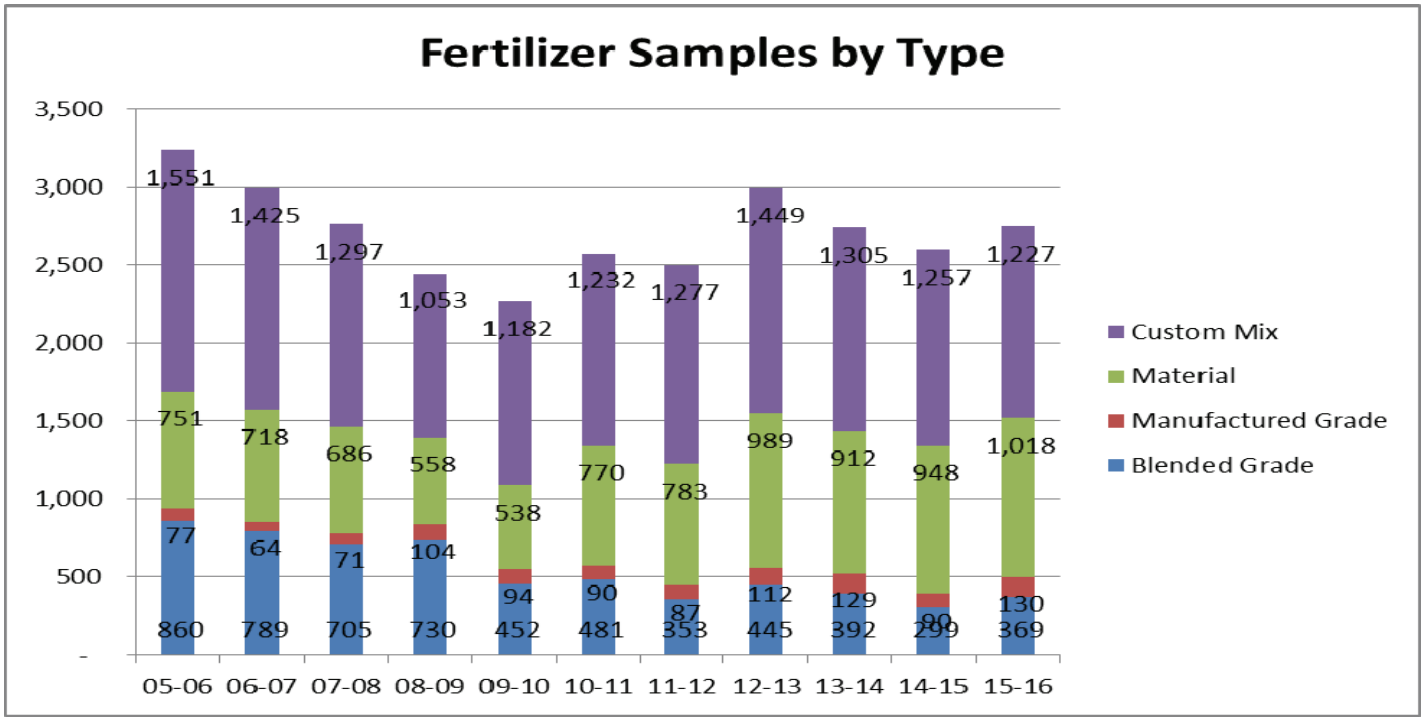
Requested By: _____ **Date:** _____
Printed Name

Firm and Address: _____

Stephen McMurry,
Director of Fertilizer and Seed Programs

2015-2016 Fertilizer Sample Review

Over the 2015 fall and 2016 spring fertilizer seasons, the Division of Regulatory Services sampled over 2,700 products for analysis. Of those samples, less than 8% experienced one or more deficiencies. The graph below shows the official fertilizer samples by type for the past 11 years.



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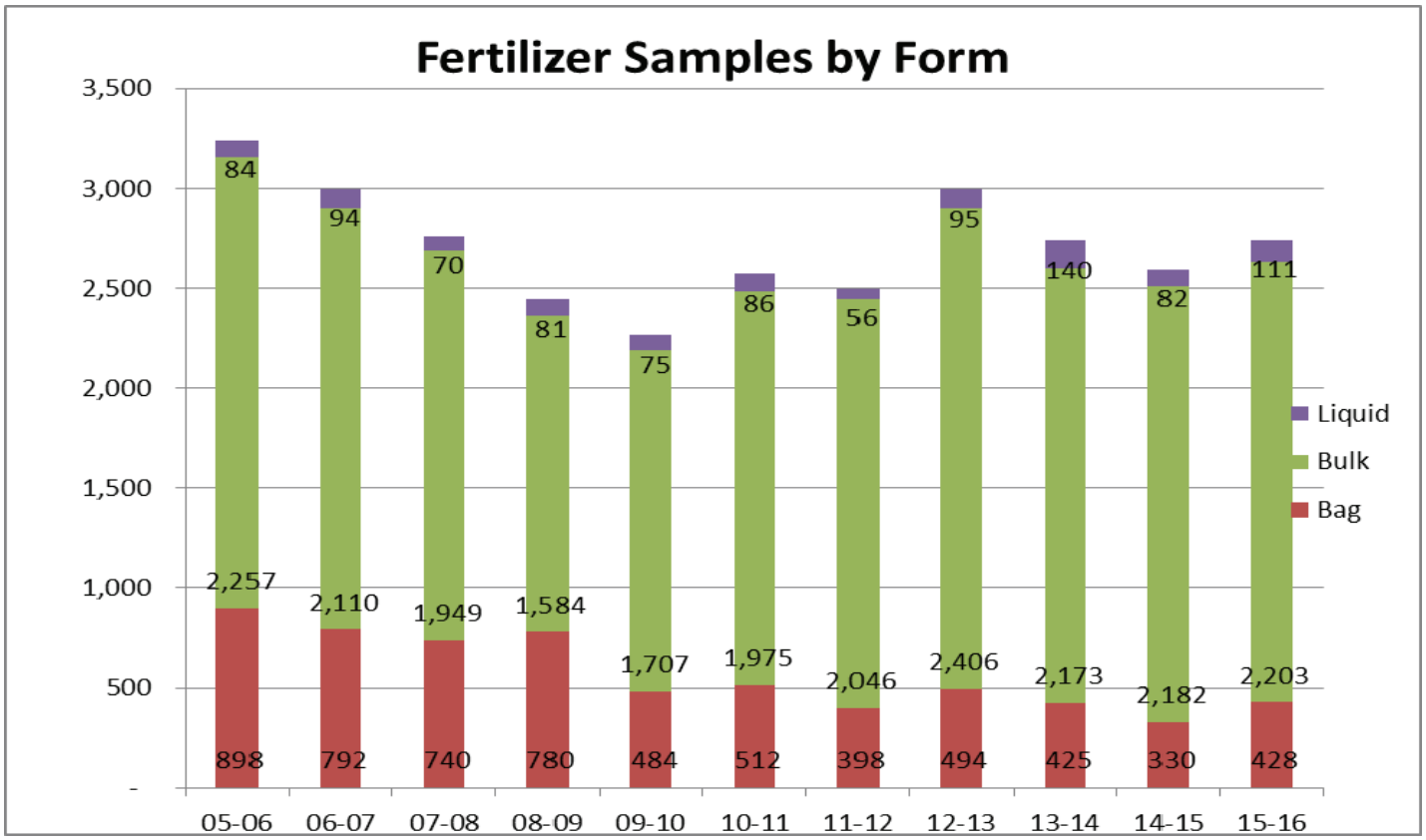
The graph below shows the official fertilizer samples by form for the past 11 years.



Stephen McMurry,
Director of Fertilizer and Seed Programs

Regulatory Services Personnel Changes

Retiring Employee

Kellye Gaither retired from Regulatory Services at the end of July. Kellye was a Systems Program Analyst and was instrumental in developing and maintaining many of the computer programs that we use in our Division. She started working here on July 18, 1988 so completed 28 years of service (yes, she was 12 when she started here).

Kellye, her husband Stewart and their daughter Madison recently moved to Scott County. She plans on starting a second career and spend more time enjoying outdoor activities such as hiking.

We appreciate Kellye's many contributions to our Division over the last 28 years and wish her well in her retirement and second career.

New Employee

Ryan Baldwin started to work with us in mid-June as a Laboratory Technician in the milk lab. He replaces Meghan Short who took a job in her home state of Ohio. Ryan has a BS in chemistry from the University of Pikeville and comes to us from Appalachian States Analytical in Pikeville where he was involved in analyzing water and waste samples from coal mines. He had previously worked for the Neogen Corporation in Lexington.

Ryan, his wife Morgan and their two-year old son Preston moved to Lexington in June. He lists UK sports as a hobby and is looking forward to the coming sports seasons.

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