Regulatory Services News

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Director's Digest

FDA posts guidance on medically important antibiotics usage in animals

We are about to complete the third year of dealing with the veterinary feed directive. As discussed in a previous edition of Regulatory News, the usage of medically important antibiotics in animal feeds has been reduced by the VFD rule. On September 23, the FDA announced the next step in the fight against antimicrobial resistance by issuing draft guidance for industry (GFI) #263 to outline the agency's recommended process for voluntarily bringing the remaining approved animal drugs containing medically important antimicrobials under the oversight of licensed veterinarians. "When Draft GFI #263 has been finalized and fully implemented, all dosage forms of all approved medically important antimicrobials for all animal species can only be administered under the supervision of a licensed veterinarian and only when necessary for the treatment, control or prevention of specific diseases," the FDA said in a statement announcing the draft guidance.

When GFI #263 is implemented, the approved marketing status of injectables, tablets, and intramammary products containing these antibiotics will be changed from over-the-counter (OTC) to prescription. Tetracyclines, sulfas, penicillin, erythromycin, and spectinomycin are among the antibiotics affected. You may view the entire list of antibiotics involved at the following website:

https://www.fda.gov/animal-veterinary/judicious-use-antimicrobials/list-approved-new-animal-drug-applications-affected-draft-gfi-263

FDA is currently accepting comments on the guidance for a 90-day period which will end on December 24. In addition, they will engage with stakeholders and state partners (such as Regulatory Services) at public events, such as meetings and conferences, to receive feedback and answer questions about the planned changes. Once the final GFI is released, FDA will allow a two-year implementation period to provide industry time to update all labels. Therefore, this guidance should be fully implemented sometime in 2022.

If you want to view the guidance document, it is available at the following link:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-263-recommendations-sponsors-medically-important-antimicrobial-drugs-approved-use-animals

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A positive GMO story

The number of positive stories about the benefits of GMO foods continue to add up. I respect anyone's views on the use of GMO foods but when I read reports like the one below, I don't understand how we can feed the world in 2050 without taking advantage of this technology to increase food production efficiency.

While not one of my favorite foods, eggplant (or brinjal as it is known in southeast Asia) is a staple in many countries. Brinjal is popular in Bangladesh but farmers struggle with insect damage, especially from the eggplant fruit and shoot borer (FSB). Because of this, conventionally grown brinjal is one of the most heavily sprayed crops in South Asia. Brinjal farmers have sprayed insecticides as many as 84 times in a growing season to protect their crops. This inspired scientists at the Bangladesh Agricultural Research Institute to develop a pest resistant variety (BT brinjal) as an alternative to insecticidal use. Studies found that Bt brinjal confers almost total protection against FSB and helps reduce infestations of other harmful insects such as beetles, mites and mealy or leaf wing bugs. Farmers still need insecticides to control other pests, but studies are under way to identify ways of controlling secondary pests and reducing use of pesticides even more.

A recent study was prepared for the US Agency for International Development (USAID) by the International Food Policy Research Institute (IFPRI) to evaluate the benefits of Bt brinjal. They found a 39% overall reduction in the quantity of pesticides used and a 51% reduction in the number of times pesticides were applied when farmers grew Bt brinjal versus the conventional variety. The IFPRI study also found that cultivation of Bt brinjal resulted in a 41% reduction in the toxicity of pesticides applied, as measured by the Pesticide Use Toxicity Score (PUTS), and a 10% reduction in the likelihood of reporting symptoms consistent with pesticide poisoning.

In addition to human and environmental health benefits, farmers planting Bt brinjal spent 47% less on applying pesticides and a 31% overall reduction in the cost of growing brinjal. In addition, farmers had a 41% increase in net yields from growing Bt brinjal. Higher yields and lower production costs resulted in a 27% increase in gross revenues per hectare with farmers realizing a gain of 38,063 taka (US $450.00) per hectare in net profits. This is significant in a country where the average annual household income is just $600.00.

"This study confirms previous studies showing that Bt brinjal can achieve its main aim, which is to improve the livelihoods of smallholder farmers in a developing country while also protecting the environment by reducing insecticide sprays," noted Dr. Anthony Shelton, a Cornell University entomologist and principal investigator of the USAID-funded, multiple-year project, Feed the Future South Asia Eggplant Improvement Partnership.

Bangladesh was the first country in South Asia to approve commercial cultivation of a genetically modified food crop. Small farmers have rapidly adopted Bt brinjal, from just 20 when first introduced in 2014 to more than 27,000 across all districts of Bangladesh.

Increased yields, increased profits, and reduced use of pesticides are strong arguments for the use of GMO crops and "all reliable evidence produced to date shows that currently available GM food is at least as safe to eat as non-GM food" (The Royal Society).

The information for this article was taken from the Alliance for Science website sponsored by Cornell University. This is a great website if you want to read more about advances in science to feed the world and can be accessed at the link below:

https://allianceforscience.cornell.edu/

Hemp testing

As most of you know, the Division of Regulatory Services is tasked with testing the THC levels in industrial hemp. By federal law, hemp must contain less than 0.30% THC before it can be marketed. This is the third growing season that we have had this responsibility. In 2017, we tested 314 samples and in 2018, we tested 567 samples. As of Monday, November 4, 2019, we have received 3,088

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samples for testing and the season is not over yet. This is certainly more than we had planned for and is putting quite a strain on our lab since we can only run about 45 samples per day and this includes any reruns (we retest any that test over the limit on the first run). We are working as fast as we can and apologize for any delay to those waiting for their results.

This many hemp samples would indicate that there will be lots of hemp byproducts available from this growing season. It would be logical to use at least some of these byproducts for livestock feed but this is still not legal until the hemp industry gets these products approved as safe for feeding. For more information on this topic, please read the article later in this newsletter concerning hemp as livestock feed.

Dr. Darrell Johnson
Executive Director

Seed Registration and Permit Renewals for 2020

The renewal process for seed registrations and permits will occur in the next few weeks. Applications will be emailed or mailed to seedsmen, seed dealers, and seed conditioners who were permitted and registered in 2019.

Firms that sell seed at retail in container sizes of 40 pounds or more are required to register as Seed Dealers. Locations that condition uncertified seed for distribution in Kentucky are required to register as Non-Certified Seed Conditioners. Those who condition only certified seed are registered as a part of the certification process under the Kentucky Seed Improvement Association.

Anyone who labels agricultural seed or agricultural seed mixtures is required to obtain a Permit to Label Agricultural Seed. Those who obtain this permit are also required to file Semi-Annual reports and pay fees based on the container size of the product. Semi-Annual reporting forms are emailed or mailed to agricultural seed permit holders at the end of each period and are required to be filed within 45 days after the end of each period.

Anyone who labels vegetable seed, flower seed, or combination mulch, seed and fertilizer is required to obtain a Permit to Label Vegetable Seed, Flower Seed, or Combination Mulch, Seed, and Fertilizer Products. These products are not subject to the Semi-Annual reporting schedule.

Fees for registrations and permits are $25 each. Locations that are required to obtain both a labeling permit and a registration or both registrations only pay one $25 fee for all. It is common for a location to be involved in conditioning seed, labeling seed and also selling seed at retail. All three applications are required, but only one $25 fee is paid. A $50 fee would only be required if both labeling permits are needed. The registration fees are waived if one or both permits are obtained.

Applications will be emailed or mailed to your location and are based on the applications that you currently have. Please complete the applications and return with the application fee stated to our office. If you have questions about this process, please contact Marilyn Smith at 859-218-2468.

Stephen McMurry,
Director of Fertilizer and Seed Programs

Testing for Contaminants in Feed Samples

In previous articles on our extensive feed sampling program, I've mentioned our goal of expanding our sampling program to include more testing for contaminants. Our philosophy has been and continues to be that compliance sampling is the heart of our feed program. We believe that compliance sampling ensures consumers that they are getting the product they paid for and aids agribusiness by promoting a level playing field in the state.

Until recently, our contaminant testing consisted of testing grains for mycotoxins, testing for drug residues in non-medicated products, measuring heavy metals, and using microscopy to visually identify contaminants. A number of state regulatory labs test pet foods for microbial contaminants and we added this capability in the fall of 2018. In December of last year, we tested our first samples for the presence of salmonella and listeria.

To date, Kentucky has limited our testing to purchased products in sealed packages. We have

sampled raw or frozen products from in-store coolers or freezers. With these samples, temperature of the cooler or freezer is recorded and temperature of the product is monitored from sampling to the lab. Microbial testing is qualitative rather than quantitative. If any viable salmonella or listeria bacteria can be cultured from the sample and we can confirm growth, the sample is considered positive for the contaminant.

While the majority of our contaminant testing has been conducted on pet treats, we have also sampled and tested complete pet foods, equine treats, goat treats, and backyard chicken feed. We've sampled products in several forms including raw, frozen, freeze-dried, and extruded. We've sampled products at pet stores, supermarkets, farm and garden stores, and online.

When a positive result is confirmed, we follow our written protocols to inform the guarantor and the distributor as soon as possible that the product in question is under a withdrawal from distribution. The distributor is instructed to remove from their shelves any remaining product from the particular lot that tested positive. We also notify our regional contacts with the Food and Drug Administration (FDA) at this time.

Dr. Alan Harrison
Director of Feed and Milk Programs

FERTILIZER PRODUCT REGISTRATION FOR 2020 IN KENTUCKY

All Kentucky fertilizer registrations and licenses expire on December 31, 2019 and must be renewed to legally sell fertilizer in the state for 2020. 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 2019, all licenses approved for 2019, and instructions for completing the task.

BE ON THE LOOK-OUT FOR YOUR RENEWAL NOTICE

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

SURVEY OF COMMERCIAL VALUES OF FERTILIZER NUTRIENTS

Over the next few weeks you will receive, or you may have already received a survey to determine the commercial values of fertilizer nutrients. Under the provisions of KRS 250.401, I am conducting a survey to determine the commercial values of the fertilizer nutrients for Calendar Year 2020. 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 responded to this survey. Please note that we want the current retail value of fertilizers in dollars per ton. All information will, of course, be held in strict confidence. You can give the survey to your respective inspector or fax to 859-257-9478 to the attention of Steve McMurry or e-mail to smcmurry@uky.edu.

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

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

Stephen McMurry,
Director of Fertilizer and Seed Programs

FDA Contract Feed Mill Inspections

The Division of Regulatory Services has a contract to perform FDA feed mill inspections. All 8 of our inspectors and myself, have FDA credentials and have attended FDA trainings to perform feed mill inspections for licensed medicated feed mills, non-licensed medicated feed mills, BSE, VFD, and cGMP part 507 inspections for those feed mills that do not make medicated feed. This year's contract has 28 firms that will be inspected. There will be 3 inspections at licensed medicated feed mills, 13 inspections at non-licensed medicated feed mills (cGMP part 225 and part 507 both), 8 at firms that do not manufacture medicated feed (these are part

507 cGMP only inspections) and 4 BSE only inspections that handle prohibited material that can not be used in ruminant feed.

All firms manufacturing medicated feed have a two-part inspection. The first part has to do with the manufacturing of safe medicated feed (cGMP part 225). This will involve the review of all drug records, the production processes and methods used to make medicated feed, and the review of any VFD records if those drugs are being used by the firm in manufacturing medicated feed. The second part of the inspection involves the cGMP part 507 inspection where we inspect the entire facility for good housekeeping, equipment, manufacturing processes, training records for employees (which must be kept for 2 years), and any other factors that could affect the ability of the firm to produce safe feed. FDA has reduced the BSE inspections that have been performed the last several years, and now the BSE inspections are limited to the firms that use prohibited materials in feed manufacturing.

The inspectors have started performing these FDA inspections, which are normally performed during the fourth quarter of the current year and the first quarter of the following year. If you have questions during these inspections, please ask our inspectors. Our goal and mission is to help and assist you to become compliant with the FDA laws and regulations.

There is one other part of the FDA contract inspections that we do not currently perform in KY. That is the Preventative Controls section of FSMA. Currently FDA is conducting that part of the inspections as our inspectors have not yet been able to attend the PC training to perform that part of the inspections. We currently have 4 inspectors scheduled to attend the preventative control training in the next 4 months and hope to have the rest of the inspection staff training in time to perform these inspections by the 2020-2021 FDA contract year.

Years of Service

I just completed my 10th year as Inspector Coordinator and wanted to recognize our inspectors for their years of service with the Division of Regulatory Services.

John Flood- 34 years
Dave Mason- 32 years
Terry Prather- 26 years
Brad Johnston- 22 years
Mark Barrow- 16 years
Warren Pinkston- 14 years
Bart Young- 9 years
Nathan Keith- 7 years

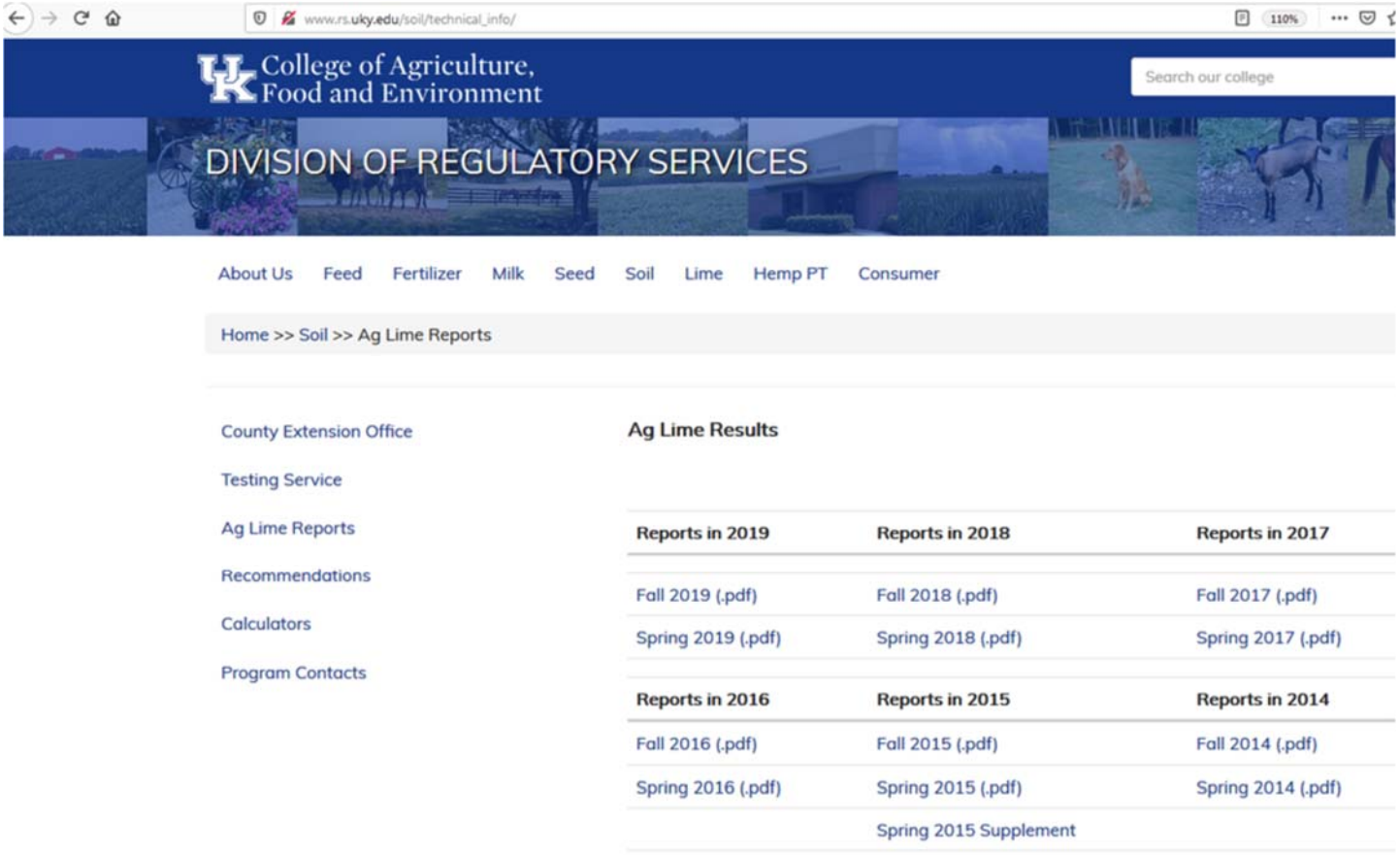
Jim True
Inspector Coordinator

Ag Lime Testing Summary Reports Available on the web

Our Division has sampled and tested Ag Lime for the Kentucky Department of Agriculture since the fall of 2016. This activity supports the Kentucky Agricultural Limestone Law and informs agricultural producers on the quality of Ag Lime sold throughout the state.

We conduct sampling and testing in the spring and fall of each year. When lime tests are complete in the lab, summary reports with results are updated on our website at www.rs.uky.edu. The page containing our summary reports is shown on the next page and can be accessed by clicking on Lime from the top menu items. In addition to the summary report posted on the website, the lime quarry is emailed or postal mailed a lab report of their results.

When searching for ag lime results be sure the web page appears with our Division header as shown on the next page. The lime reports may also be posted by county extension office web sites that may not be updated with the latest reports. Also, make sure you refresh the web page after the report appears. You may have an older version report stored on your local computer that will appear. Most browsers have as a circular arrow to hit (↻) at the very top that will refresh the page with the latest report.



Dr. Frank Sikora
Director of Laboratories

Proficiency Testing Program for Hemp

Our Division is in our third year of testing Hemp for the Kentucky Department of Agriculture to ensure the plants meet the legal definition of hemp by having THC concentration less than 0.3%. The 2018 Farm Bill passed last December has allowed states to move from allowing hemp to be grown in pilot programs to fully allowing commercial production of the crop with regulatory control. Many aspects of hemp regulations are moving faster than the knowledge of the crop that has not been in commercial production for 82 years. One aspect is the analytical testing to ensure THC concentration is less than 0.3%.

We began a proficiency testing program last fall to help labs ensure their methods for testing hemp for THC are adequate. The same hemp sample is sent out to several labs with each lab providing their test results for the sample. The test results are compared with one another to determine how similar or dissimilar they are. Reports are generated for each lab providing them a score for how well their results agree with the average of all the results and how well they can repeat their results.

The program has grown from 40 labs in 2018 to the current number of 66 labs. Half of the labs are state regulatory labs and half are private labs. Twelve labs are in Kentucky.

The program has provided information on how much variation exists amongst labs. We have found samples with an approximate average of 0.3% THC to range from 0.2 to 0.4% THC from the participating labs. This information is vital in defining the current state of the art for THC testing and provides a measurement on improvements made in the future.

Information and statistical reports from the program are available on our website at www.rs.uky.edu by clicking on Hemp PT from the top menu items.

Dr. Frank Sikora
Director of Laboratories

Hemp is not (yet) an approved feed ingredient

We continue to receive questions about the use of hemp in animal feed. The following article is reprinted from Progressive Cattle and does an excellent job of describing the current status of Hemp as a feed ingredient. The Kentucky policy may be found on our website in the feed section.

It goes without saying that hemp production is currently a hot topic in agriculture. As is the case with almost all other agricultural or food industries where harvest, refinement or processing results in a residue or byproduct, there is also considerable interest in potential uses for hemp and its byproducts as animal feed ingredients – particularly for cattle.

While the information contained in the 2018 Farm Bill paved the way for a dramatic increase in hemp production, it did not grant permission to use hemp or any of its byproducts in animal feeds. As such, there is currently no outlet through which hemp or any of its byproducts can legally be fed to animals – including cattle.

Who regulates animal feeds?

Animal feeds – and therefore any substance or ingredient included in animal feeds – are jointly regulated by the U.S. Food and Drug Administration (FDA), the Association of American Feed Control Officials (AAFCO, which is primarily made up of state and federal regulators) and each respective state's department of agriculture. In a nutshell, the FDA and AAFCO establish regulations that apply to anything that is used in animal feeds, which are enforced by each respective state. Then individual states have the ability to establish and enforce additional regulations that apply to products that are marketed or fed within their regulatory jurisdiction.

How does a potential feed ingredient become approved to be fed to animals?

Before being legally fed to animals, any feed ingredient that is not considered by the FDA to be a new animal drug must undergo a scientific review process to ensure that the product is safe to both animals and humans when used as an animal feed ingredient. Once the ingredient has passed this scientific review process, it receives an official feed ingredient definition. Depending upon the type of ingredient and its potential use, the three possible routes through which the ingredient definition is received include:

1. A successful food additive petition to the FDA
2. Receipt of a letter of no questions from the FDA in response to an application for a generally recognized as safe (GRAS) designation
3. An approved application for an official AAFCO ingredient definition

Successful completion of any of these routes results in an ingredient definition contained within AAFCO's official publication, which is published annually. The latter option – application for an official AAFCO ingredient definition – is by far the most common route through which a feed ingredient becomes approved for use in animal feeds.

Why can't hemp or its byproducts be fed to animals?

It is currently illegal to feed hemp or any of its byproducts to animals in the U.S. because comprehensive materials that document the safety of hemp or its byproducts when used as animal feed ingredients have not been approved through either of the three routes. Therefore, there are currently no AAFCO ingredient definitions that apply to hemp or any of its byproducts. In the current state, this makes any food animal that was fed hemp or hemp byproducts, along with any food products obtained from that animal, adulterated. Any animal or animal products that enter commerce are the legal responsibility – and therefore the liability – of the producer. This doesn't mean that applications have failed (which may or may not be true), it just means that the government has not yet received the information necessary to ensure animal and human safety, and therefore it has not yet given the green light on feeding hemp or any of its byproducts. The most recently updated (May 1, 2019) guidelines for use of hemp in any feeds can be found on AAFCO's website.

Will it always be illegal to feed hemp or its byproducts to animals?

Not necessarily, and only time will tell. It is quite possible that hemp or its byproducts may be approved for use as animal feed ingredients in the not-so-distant future. But for now, let's keep hemp and its byproducts out of the feed bunk until they become AAFCO-approved feed ingredients, as we should do with any ingredient that has not been evaluated to confirm animal and human safety. Our nation – and many others for that matter – depend on us to provide safe, wholesome beef products.

Jason Smith
Assistant Professor and Extension Beef Cattle Specialist
Department of Animal Science
Texas A&M AgriLife Extension

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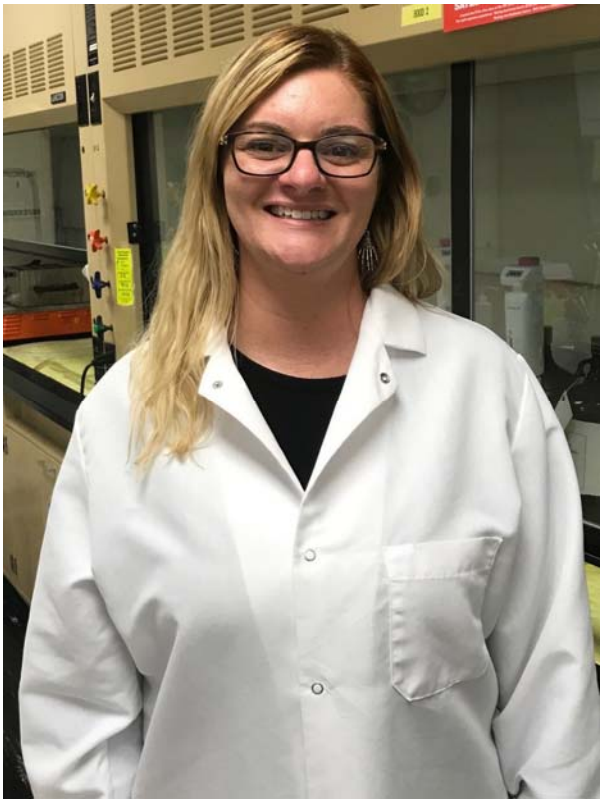


We are happy to welcome Lisa Burke as the newest employee of Regulatory Services. Lisa started working in our Milk Laboratory in late October. Lisa is a native of Frankfort and has a degree in Biology from Kentucky State University. She has spent the last seven years as a Biological Laboratory Technician for the USDA-APHIS Surveillance and Regulatory Laboratory in Frankfort. Lisa brings lots of skills with her, is anxious to learn new laboratory techniques, and will be a great asset to our milk lab.

Lisa continues to live in Frankfort with her 5-year old daughter Bella and their cat Grumpy. In her spare time, she enjoys shopping, going to concerts and spending time with her daughter.

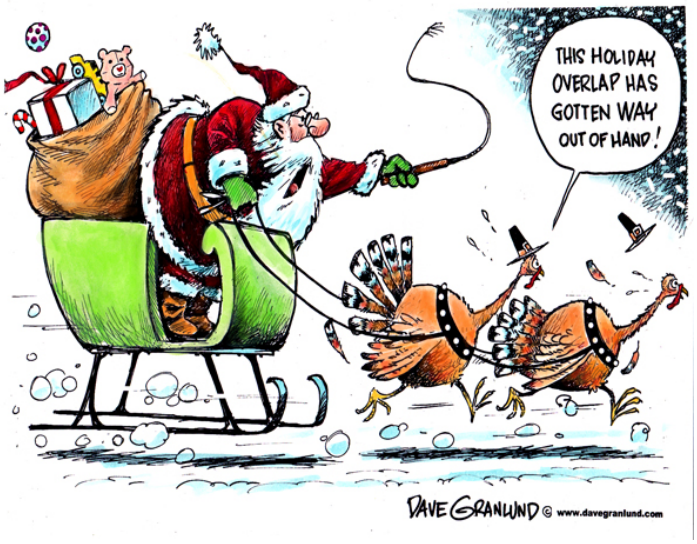
Upcoming Meetings

Kentucky Agribusiness Summit
(ABAK Annual Meeting)
November 5-7
Holiday Inn Hurstbourne
Louisville, KY
https://kyagbusiness.org/

Kentucky Farm Bureau Annual Meeting
December 4-7, 2019
Galt House
Louisville, KY

AAFCO Mid-Year Meeting
January 21-23, 2020
Albuquerque, NM
https://www.aafco.org/Meetings

AAPFCO Winter Annual Meeting
February 16-21, 2020
New Orleans, LA
http://www.aapfco.org/meetings.html



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

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Regulatory Services