Regulatory Services News

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Director's Digest

Appreciate the food safety we enjoy today

We do read fairly often today of food recalls due to contamination or adulteration but food safety today is so much better than it was at the turn of the century when nobody was monitoring what was sold to the consumer. In the late nineteenth century many people were moving to the cities for industry jobs and this took them away from the idyllic picture many have of people raising and consuming their own food including having the family milk cow. This was also before refrigeration and food manufacturers were embracing the rise of industrial chemistry.

I recently finished reading the book "The Poison Squad" which chronicles the efforts of Dr. Harvey Wiley to bring about pure food and drug legislation. Dr. Wiley became chief chemist of the United States Department of Agriculture in 1883 and fought valiantly for pure food laws until finally the Pure Food and Drug Act was passed in 1906. As I discussed in an earlier Director's Digest, the UK College of Agriculture was responsible for this work in Kentucky until 1918 when it was turned over to the state government in Frankfort. Some examples of food safety issues faced back then will help you appreciate the work done today by the USDA, FDA, and State Regulatory Agencies to keep our food supply safe. I also believe these efforts have contributed greatly to the rise in the average life span over the last 100 years.

My morning doesn't start out right unless I have a glass of cold milk and as long as I observe the "best by date" I have the utmost confidence that today's milk is safe and nutritious. However, drinking milk in the city could be a dangerous proposition in the late 1800's. Quoting from The Poison Squad: "Dairymen, especially those serving crowded American cities in the nineteenth century, learned that there were profits to be made by skimming and watering down their product. The standard recipe was a pint of lukewarm water to every quart of milk-after the cream had been skimmed off. To improve the bluish look of the remaining liquid, milk producers learned to add whitening agents such as plaster of paris or chalk. Sometimes they added a dollop of molasses to give the liquid a more golden, creamy color. To mimic the expected layer of cream on top, they might also add a final squirt of something yellowish, occasionally pureed calf brains."

Milk also tends to rot quickly without refrigeration and industrial chemistry had provided new preservatives such as formaldehyde. Processors started employing formaldehyde solutions, sold under innocuous names such as Preservaline. This was not only used in milk but to restore decaying meats as well. The use of formaldehyde was attributed to the death of many children prior to regulation.

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Adulteration of food was common in other food products as well. Honey was often found to be thickened, colored corn syrup. Vanilla extract was found to be a mixture of alcohol and brown food coloring. Strawberry jam could be sweetened paste made from mashed apple peelings laced with grass seeds and dyed red. Pepper, cinnamon, or nutmeg were frequently laced with fillers such as charred rope, pulverized coconut shells, charred rope, or occasionally floor sweepings. Coffee could be largely sawdust, or wheat, beets, beans, peas and dandelion seeds which were scorched black and ground to resemble coffee.

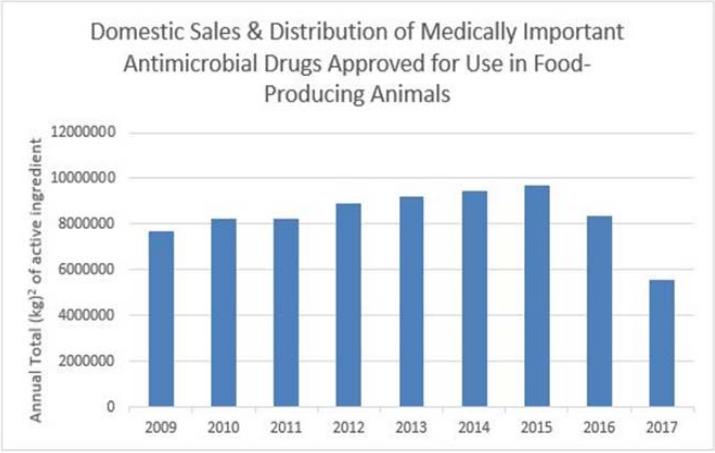
Even our beloved bourbon from Kentucky was subject to adulteration. Fake whiskey was often made by blending ethanol with water and tinting it brown with products such as tobacco extracts, tincture of iodine, burned sugar, or prune juice. Colonel Edmund James Taylor of Kentucky, namesake of Old Taylor bourbon, was a distiller who fought to distinguish bourbon from the fakes. His efforts and those of others led to passage of the Bottled-in-Bond Act in 1897. This law attempted to encourage basic quality standards. It stated that each bottle of spirits could be marked with a green "bonded" seal from the government if it was aged for at least four years in a supervised federal warehouse. Bonded also meant that the whiskey was labeled for proof and the location of the specific distillery.

You would think that documenting all these practices would convince the federal legislature to pass laws protecting consumers but political pressure was evident even back then and efforts were strongly opposed by the food manufacturers of that time. In an effort to obtain passage of such laws, Dr. Wiley recruited volunteers from the Department of Agriculture to participate in trials involving consumption of known food additives at the time such as borax (used for butter and meat preservation), salicylic acid (used as a preservative in wine and beer), sulfurous acid, benzoates, formaldehydes, copper sulfate (often used as a coloring agent in peas), and salt peter. These volunteers were twelve healthy young men who would agree to consume three meals per day in a laboratory kitchen in the basement of the Bureau of Chemistry at the USDA. This group was quickly labeled the "Poison Squad" by the Washington Post and Dr. Wiley was nicknamed "Old Borax". In the first trial, six members of the poison squad consumed normal meals while the other six consumed the same meals plus capsules containing increasing amounts of Borax. Researchers monitored the effects by collecting chemical and physiological data. The effects of borax included nausea and loss of appetite, symptoms resembling those of influenza and overburdened kidneys. These trials started in 1902 and continued for five years and helped contribute to passage of the Pure Food and Drug Act in 1906. There were still some deficiencies in consumer protection from this act but consumers voices were becoming stronger and the Food, Drug and Cosmetic Act was passed in 1938 which strengthened the laws and led to formation of the Food and Drug Administration.

Certainly trials conducted by the "Poison Squad" would not be allowed today but each of us owes a debt of gratitude to these young men for their contribution to the food safety we have today. Although there are some many of us may question, most regulations exist for a good reason and we certainly need to recognize that consumers expect a safe and wholesome food supply. If you are looking for a good read on these cold winter nights, I highly recommend "The Poison Squad".

Antibiotic usage declines

The Veterinary Feed Directive went into effect two years ago this past month in an effort to reduce the use of medically important antibiotics in food animal production. The FDA released a report in December announcing that domestic sales and distribution of all medically important antimicrobials intended for use in food-producing animals decreased by 33 percent between years 2016 and 2017. The peak year for sales and distribution of these antibiotics was 2015 and the reduction has been 43 percent since that year. A graph depicting this is shown below:



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When the agriculture and animal health communities made the commitment several years ago to reduce the use of medically important antibiotics for growth promotion and feed efficiency, critics dismissed it as window dressing and predicted it would have minimal impact. This FDA report is clear evidence otherwise. One concern I had when this was implemented was that we would not show a reduction in use and this would result in further reduction in our ability to use antibiotics to treat sick animals. There may still be further regulations but hopefully this shows we can use antibiotics responsibly and allow us to keep them for prevention and treatment of disease.

For years we used antibiotics such as chlortetracycline in feed to help cover some of our deficiencies in management. Restriction in use of these products has made us reevaluate our management and look to other ways to prevent disease and improve growth. This hasn't been easy but has proved we can reduce the use of antibiotics responsibly.

It is hopeful that consumers and the food service industry will take note of these results. We often see reports of food service companies instituting a complete ban on the use of antibiotics on farms providing animals for them. This has limited the ability of farmers and veterinarians to address animal suffering as animals treated for an illness can't be sold. Meanwhile, there are companies who reject the use of antibiotics for growth promotion and/or restrict the use of medically important antibiotics but allow animals to be treated for illness and suffering with other antibiotics. This would appear to be a much more sensible approach and one I hope more food service companies will follow.

Consumers demand reduced use of medically important antibiotics in animals and hopefully the agriculture community will use this report as proof that we hear them. We should let them know that use of these antibiotics has decreased thirty-three percent since 2016 and forty-three percent since 2015.

Antibiotics are now used for the same purpose in animals as they are in people which is for the prevention and treatment of illness. The agriculture community has shown their commitment to responsible use and retaining our ability to use them when needed is key to animal welfare.

Dr. Darrell Johnson
Executive Director

Proposed Regulation Updates/Changes for the Fertilizer Program

The Fertilizer Law's Regulations have not been updated since 2000. In order for the regulations to stay in good standing in regard to Kentucky's Sunset Law, updates are needed. Below is a summary of potential changes to the Kentucky Fertilizer Law Regulations. Please contact me at smcmurry@uky.edu or 859-218-2440 if you have any questions. We hope to get these submitted by mid-March for consideration:

12 KAR 4:080. Plant Nutrients
- Add Nickel (Ni) at a minimum concentration of 0.001% to the list of acceptable micronutrients
- Regulation name change from "Plant Nutrients" to "Plant Nutrients Registration and Guarantees"
- Establish by reference our Registration Forms

12 KAR 4:090. Guaranteed Analysis
- Bring in 12 KAR 4:160

12 KAR4:100. Slowly Released Nutrients
- No change in regulation just updating the format

12 KAR 4:110. Terms and Definitions
- Title will change to "Definitions"
- Delete all current definitions
- Reference the Association of American Plant Food Control Officials (AAPFCO) definitions of the 2019 Official Publication

12 KAR 4:120. Definition of "Percentage."
- No change in regulation just updating the format

12 KAR 4:130. Investigational Allowances
- No change in regulation just updating the format

12 KAR 4:140. Monetary Penalties
- No change in regulation just updating the format

12 KAR 4:160. Guaranteed Nutrients
- Move to 12 KAR 4:090. Guaranteed Analysis

Steve McMurry
Director of Fertilizer and Seed Programs

Feed Facility Inspections under Food Safety Modernization Act Regulations – Part 4

In previous newsletters, I presented an introduction to feed facility inspection under The Food Safety Modernization Act (FSMA) and reviewed the 8 sections of 21 CFR Part 507 Good Manufacturing Practices (GMP's). With a final compliance date for Good Manufacturing Practices of September 17, 2018, all facilities, regardless of size, that manufacture, process, pack, or hold animal food will need to comply with these GMP regulations now.

To review, the 8 sections in 21 CFR Part 507, Subpart B are: 1) Personnel, 2) Plant and grounds, 3) Sanitation, 4) Water supply and plumbing, 5) Equipment and utensils, 6) Plant operations, 7) Holding and distribution, and 8) Holding and distribution of human food by-products for use as animal food. This article will address the record keeping requirements (subpart F) of the Part 507 Good Manufacturing Practices. This is my condensed version of the record keeping regulations.

Records subject to the requirements of this subpart – 21 CFR 507.200

- All records required by this part are made promptly available to a duly authorized representative of the Secretary of HHS for official review upon request.

General requirements applying to records – 21 CFR 507.202

- Records are kept and contain actual values and observations obtained during monitoring and verification activities.
- Records are accurate, indelible, legible, created concurrent with performance of activity documented and detailed.
- All records identify plant or facility, date, time of the activity documented, signature or initials of person performing activity, and identity of product and lot code, if any.

Requirements for record retention – 21 CFR 507.208

- All records are retained at the plant or facility for at least 2 years after the date they were prepared.
- Records that relate to equipment or processes are retained by the facility for at least 2 years after their use is discontinued.

As of January 1, our inspectors have conducted 17 of the 24 scheduled GMP inspections under FSMA regulations (21 CRF Part 507) as part of our annual inspection contract with FDA. These inspections have included visits to both non-medicated and medicated feed mills. The total inspection time for these GMP inspections has averaged about 9 hours. With two inspectors for each inspection, you can expect our inspectors to spend at least a half day at the mill on the 507 GMP inspection. If the mill produces medicated feed, they are likely to spend the better part of a day at the mill.

Here are some of the most common areas where our inspectors have found room for improvement:

- Training records (507.4)
- Pest control, particularly preventing/ minimizing entry of pests (507.17 & 507.19)
- Protecting bulk feed storage from contamination (507.17)
- Identification of feed, especially rework feed (507.25)
- Proper labeling of trash to prevent contamination of feed (507.19)
- Securing covers on equipment to prevent contamination of feed (507.22)

Final Thoughts

The recurring theme in these regulations is to ensure that firms are manufacturing, processing, packing, and holding animal feed in a manner to prevent contamination. I mentioned this in the earlier articles and it bears mentioning again. FDA has structured these regulations to provide flexibility in meeting the requirements. The last point is that you can expect a strong emphasis in future inspection on monitoring progress towards meeting the requirements of the regulations. Initial inspections will have an educational focus but will also be documenting areas where improvements are needed.

For more information, you can download the regulations or the guidance for industry documents.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=507

https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499200.pdf

Dr. Alan Harrison
Director of Feed and Milk Programs

COMMERCIAL FERTILIZER VALUES FOR 2019

Commercial fertilizer values are determined and published each year. A state-wide survey was conducted in December 2018 to determine the averages for 2019. Under the provisions of Chapter 250.401 of the Kentucky Fertilizer Law, the following unit values are announced for use in determining and assessing penalties of deficient fertilizer. They represent the average of responses from throughout the state for retail value of bulk mixed fertilizers. The value of most nutrients has increased since the survey conducted last year, the current values are listed below.

NUTRIENT	DOLLARS/UNIT (20 LBS.)
Total Nitrogen (N)	$9.44
Avail. Phosphate (P_2O_5)	$8.60
Soluble Potash (K_2O)	
*Tobacco (low Cl)	$14.13
*Non-Tobacco	$6.30
Calcium (Ca)	$5.41
Magnesium (Mg)	$33.09
Sulfur (S)	$9.40
Boron (B)	$122.18
Copper (Cu)	$166.67
Iron (Fe)	$13.81
Manganese (Mn)	$35.71
Molybdenum (Mo)	$20.20
Zinc (Zn)	$53.16

Calculation Note:

(1) The *N* value for DAP & MAP was assigned from anhydrous ammonia (AA).

(2) The value of P from DAP and MAP was calculated using the assigned value of *N* from AA.

(3) The final values for *N* and P are weighted averages based on FY 18 (distributed) tonnage for ammonium nitrate, Urea, DAP, TSP, MAP, and ammonium sulfate.

If you have any questions, please call me at (859)-257-2785; or, email: smcmurry@uky.edu

Steve McMurry
Director of Fertilizer and Seed Programs

Inspector News

Summary of 2018 Inspections and Sampling

Our inspection staff has eight inspectors that are responsible for inspections and sampling at any location in Kentucky that manufacture or sell feed, fertilizer, or seed to consumers. They also sample lime at all lime quarries located in the state that produce agricultural lime. In addition, we have one inspector that is responsible for inspecting milk haulers and sampling milk produced by Kentucky dairy farmer's as it is delivered to the milk processors.

For 2018, our inspectors collected 2,924 feed samples from feed manufacturers, retail stores, and specialty stores. This includes 1,461 livestock feed, 252 ingredient samples for products used in the manufacturing of finished feeds, and 1,211 pet and specialty pet food samples from any firm that manufactures pet food in Kentucky or any retail store that sells pet food. There are a total of 226 feed manufacturing facilities in Kentucky and 880 retail location that sell either livestock or pet food.

There were 2,688 fertilizer samples collected in 2018 from fertilizer blenders and retail stores. These would include all agriculture stores, lawn and garden centers, and specialty locations. These samples include 1,188 custom mixed samples, 1,068 bin

materials, 360 bagged fertilizers, 94 liquid fertilizers, including some specialty fertilizer and ingredients used in manufacturing other complete fertilizers. There are 155 fertilizer locations in Kentucky that blend fertilizer and 584 retail locations that sell fertilizer of some kind.

In regards to seed, there were a total of 1,522 seed samples collected last year from seed distributors or retail locations. These would include all agriculture seed, lawn and garden seed, and vegetable seeds, plus some other specialty seeds such as native grasses. There are 43 seed labelers in Kentucky and 719 retail locations that sell seed.

Inspectors collected 132 lime samples last year from 75 lime quarries.

The milk program is responsible for sampling milk from the farmer to the processor, to ensure that the farmer is paid for the correct weight of milk sold. Our milk inspector collected 1,883 milk samples from 304 loads of Kentucky produced milk. In Kentucky there are about 500 dairy farmers and our goal is to try and collect samples from each farmer that producers milk in Kentucky. We test these milk samples for quality.

FDA Contract Feed Mill Inspections

The Division of Regulatory Services has a contract to perform FDA feed mill inspections. All of our inspectors, including myself, have FDA credentials and have attended all the FDA trainings to perform FDA feed mill inspections for licensed medicated feed mills, non-licensed medicated feed mills, BSE, VFD, and cGMP507 inspections for non -medicated feed mills. This year we have inspections at 28 Kentucky feed mills and are in the process of completing these in February.

If you have questions about any of these FDA inspections and all of the FSMA requirements please just ask your inspector for help or give me a call at the office.

Jim True
Inspector Coordinator

Updates to University of Kentucky Division of Regulatory Services' Laboratory Capabilities

Salmonella has been recognized as a major and important foodborne pathogen for humans and animals over more than a century, causing human foodborne illness as well as high medical and economical cost. There are many different methods to choose from based on the scientific principle applied: Conventional culture methods, immunology-based assays, nucleic acid-based assays, miniaturized biochemical assays, and biosensors. The conventional culture methods are very time consuming and labor intensive. When looking for microbiological contaminants, in order to prevent animal and human illnesses and more importantly deaths, a rapid method for detecting these microbiologicals is necessary.

As we are moving forward implementing ISO 17025 Quality SOPs in our laboratories, we are also adding to our contaminant testing capabilities. Currently, we have the capability to test feeds and feed ingredients for trace level antibiotics, heavy metals, and mycotoxins. In order to further protect the producers, consumers, and animals, we purchased a VIDAS® from bioMerieux, Incorporated to be used to screen for the presence of *salmonella species* and *listeria monocytogenes* in pet foods, pet treats, animal feeds, and their ingredients.

At the end of summer in 2018, we verified 2 screening methods (AOAC 2013.01 and AOAC 2013.11) and 2 confirmation methods (AOAC 978.24 and AOAC 2012.02) to detect and confirm the presence of *salmonella* sp. and *listeria monocytogenes* in animal feeds and their ingredients. These two bacterium cause food borne illness and pose a health risk to animals or humans who handle the contaminated feeds. We work closely with our Director of the Regulatory Feed and Milk Program so that our laboratory capabilities match what our Feed Director Goals are.

We have begun implementing our ISO quality Standard Operating Procedures in all of our laboratories. This is something that is a process over a time period and will not happen overnight. As we move towards ISO 17025 accreditation, adopt the Management Quality System, and follow our documentation and sample handling procedures, the big picture of seeing the unbroken chain of custody and sample handling procedures really comes into focus. We will continue moving forward towards meeting the ISO 17025 accreditation milestones and increasing our laboratory capability.

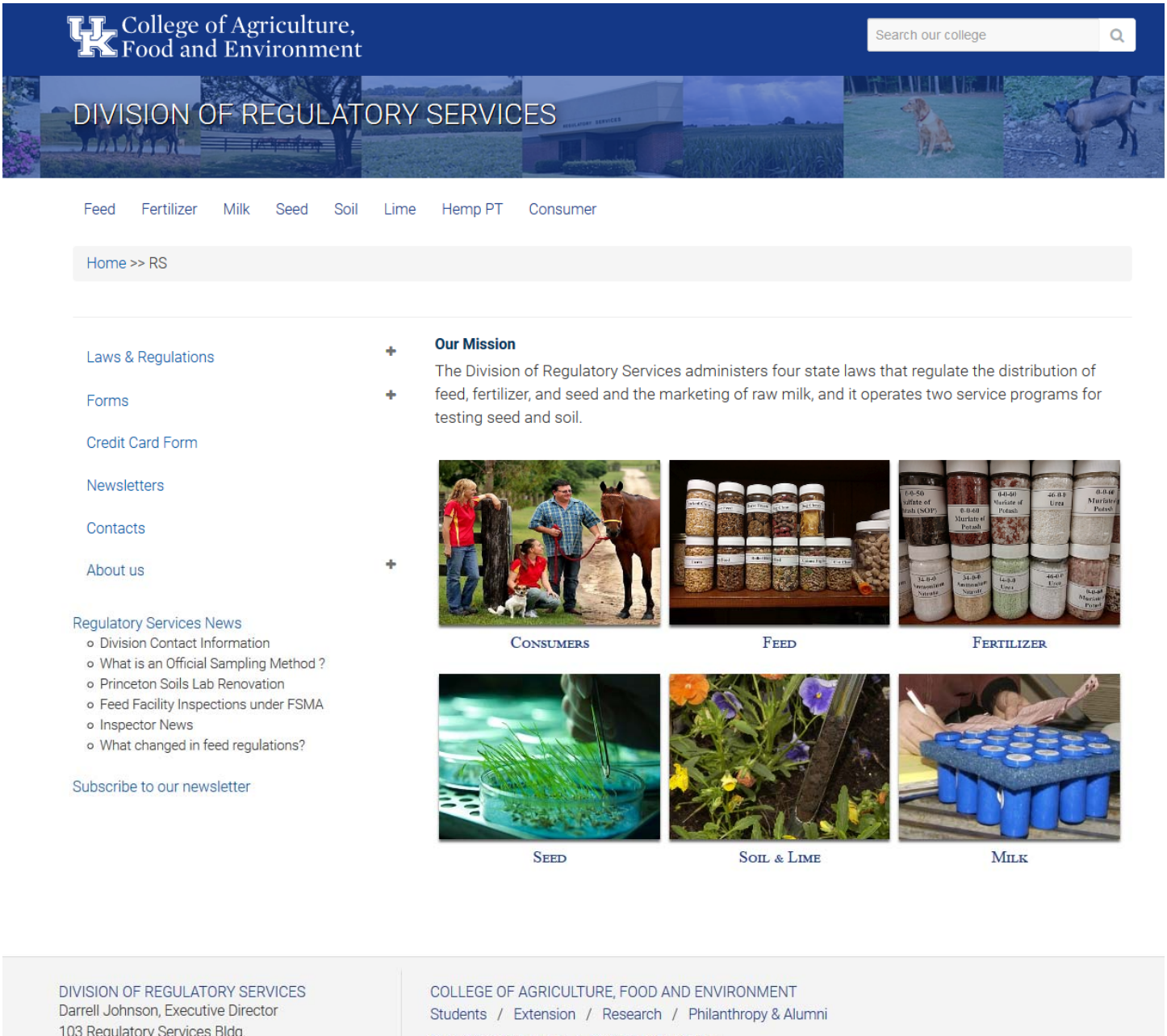
Dr. Sharon F. Webb,
Director, Quality Program

Regulatory Services New Webpage

It has been a job much more complicated than I thought, but Regulatory Services should have our new website up this month. It will be at our same address of www.rs.uky.edu/ but will look much different. The front page of the new website is shown below. Not only will it look more modern but we have added some new areas for consumers to provide them information on pets, livestock, seed, and gardening. It is also our hope that we are providing the information needed by agribusinesses to answer their regulatory questions and provide reports they will find useful.

We hope you will check out our new website and provide us feedback on what you find useful and what needs some improvement. There will be some kinks at the start and some parts may not be finished but we wanted to go ahead and roll out this upgrade. You can navigate the site by clicking on the pictures or the type printed in blue.

Dr. Darrell Johnson
Executive Director



Rajna Tosheva-Tounova wins 2018 Poundstone Award.

Dr. Rajna Tosheva-Tounova was awarded the Poundstone Award at our 2018 Christmas luncheon. Rajna is a research analyst in our HPLC laboratory and among her duties is responsible for analysis of mycotoxins and drugs.

One of her nominators wrote about Rajna that "*she takes it upon herself to delve deeper into research to learn more of why something will work rather that treat a method like a recipe. She really is an excellent analyst. She always stresses the importance of what the Division does and wants to ensure that the part she contributes in correct and defensible.*"

Rajna is a native of Bulgaria and has a Ph.D. in Biochemistry from the Bulgarian Academy of Sciences. She has worked at the University of Kentucky since 1994 and came to the Division of Regulatory Services in 2007.

Rajna's work is very important to what we do in our feed program and we appreciate her attention to details and desire to produce accurate results.

Rajna lives in Lexington and in her spare time enjoys riding a bike and water aerobics to stay fit. She has always enjoyed traveling back to Bulgaria and Europe in general. She also enjoys spending time with her granddaughters who will both be graduates of the University of Kentucky.

History of the Poundstone Award

The Poundstone Award was created to honor an outstanding employee in the Division of Regulatory Services. The award is named in honor of Bruce Poundstone, who was Director of Regulatory Services for many years. He was nationally renowned for his leadership and innovations in the feed, fertilizer and seed regulatory arena. He was founder of the Feed Microscopy Association, started the AAFCO Feed Control Seminar, and was a participant in the development of the GMP concept for feed manufacturing. Mr. Poundstone was a distinguished leader in the Association of American Feed Control Officials, the Association of American Plant Food Control Officials and the Association of Southern Feed, Fertilizer and Pesticide Control Officials. The Regulatory Services building is named in his honor.

Previous Poundstone Award Winners

Recipient	Year	Department
Marilyn Smith	2017	Seed Department
Gary Coleman	2016	Feed/Fertilizer Lab
Stephany Chandler	2015	Reception/Data Entry
June Crawford	2014	Fertilizer Department
Colleen Steele	2013	Soils Lab

Upcoming Meetings

AAPFCO Winter Annual Meeting
February 10-13, 2019
Hyatt Regency
Albuquerque, New Mexico
http://www.aapfco.org/meetings.html

Kentucky Dairy Partners Meeting
February 26-27, 2019
Slone Convention Center
Bowling Green, Kentucky
http://www.kydairy.org/ydpkdp-conference.html

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