

Regulatory Services News

Vol. 64, No. 2

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

Summer 2021

Director's Digest

One Year Later

On March 12, 2020 we held our annual Milk Advisory Board meeting in the E.S. Good Barn here on campus. We were hearing lots of rumblings about the coronavirus but little did we realize that would be our last in person meeting for 2020. One year later, we still haven't had any in-person meetings but we do hope to by summer. The University of Kentucky has held a mixture of virtual and in-person classes this year but plans to go back to normal classes this coming fall. UK football has even given me the opportunity to renew my tickets for the 2021 season and hopes to be back at full capacity.

The Covid pandemic changed all our lives. Early on, agriculture was deemed essential and Regulatory Services was told to continue performing our duties. We scrambled to rearrange office and lab schedules to keep everyone safe and to provide inspectors with the PPE they needed to maximize their safety. Our inspectors were conscientious of safety requirements at businesses they inspected and we delayed FDA inspections we normally do in the fall to this spring. We did have a few employees infect-

ed with the Covid-19 virus but isolation procedures kept it from spreading to other employees and all recovered well.

I was compiling a summary of our 2020 work recently and was glad to see that even with all the coronavirus restrictions during the last year our regulatory sample numbers were very similar to previous years and this is a good testament to the dedication of our employees. The following tables show program numbers over the last three years.

Feed Program

We have approximately 1,200 companies offering feed for sale in Kentucky. Inspectors will pull samples on an inspection visit on large package or bulk items. For packages under ten pounds, they will purchase these. We have also started purchasing samples from online retailers. Over the last three years we have inspected over 900 facilities each year and analyzed over 3,200 feed samples. Thirty to forty percent of these samples will be pet food. Unofficial samples are those not pulled by our inspectors and include those submitted by individuals or county

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Regulatory Services
College of Agriculture, Food and Environment

Division Contact Information**Phone: (859) 257-2785****Fax: (859) 323-9931****Executive Director**

Dr. Darrell D. Johnson

darrell.johnson@uky.edu**Auditor**

Robert Counts, Jr.

robert.counts@uky.edu**Feed & Milk Programs**

Dr. Alan Harrison-Director

alan.harrison@uky.edu

Kristen Green, Registration Specialist

kristen.mary.green@uky.eduJenny Combs, Animal Feed Regulatory Program
Standards Specialistjennifer.combs@uky.edu

Bob Hickerson, Milk Inspector

rhickers@uky.edu

David Tompkins, Feed/Fertilizer Lab Supervisor

dtompkin@uky.edu

Kristin Brock, Milk Laboratory Supervisor

kristin.brock@uky.edu

Michelle Young, Staff Assistant Feed

michelleyoung@uky.edu

Stephany Pasley, Staff Assistant Milk

stephany.chandler@uky.edu**Fertilizer & Seed Programs**

Stephen McMurry-Director

smcmurry@uky.edu

Jonathan Collett, Seed Laboratory Supervisor

collett88@uky.edu

June Crawford, Staff Assistant Fertilizer

june.crawford@uky.edu

Fax: (859) 257-9478

Marilyn Smith, Staff Assistant Seed

mm.smith@uky.edu

Fax: (859) 257-7351

Inspector Coordinator

Jim True

jim.true@uky.edu**Inspectors**

Mark Barrow

mcbarr2@uky.edu

Nathan Keith

nathan.keith@uky.edu

John Flood

jflood@uky.edu

Brad Johnston

bjohnsto@uky.edu

David Mason

dwmason@uky.edu

Warren Pinkston

wwpink00@uky.edu

Terry Prather

tprather@uky.edu

Bart Young

bart.young@uky.edu**Laboratories & Soils Program**

Dr. Frank Sikora-Director

fsikora@uky.edu

Dr. Solomon Kariuki-Lab Manager

skka222@uky.edu

Diane Hunter, Soils Lab Supervisor, Lexington

diane.hunter@uky.edu

Amanda Martin, Soils Lab Supervisor, Princeton

amanda.martin2@uky.edu**Quality Control Director**

Dr. Sharon Webb

sfwebb2@uky.edu

Lauren Smith, ISO 17025 Accreditation Specialist

lauren.omara@uky.edu

Director's Digest, continued

agents.

We usually analyze multiple nutrients in each product as shown by the number of lab analyses. Samples passed are those where all nutrients passed for that sample. Components passed represents each nutrient or medication analyzed. I am always amazed at the number of feed products registered for sale within our state and how many new ones there are each year.

Feed Program			
Year	2018	2019	2020
# Inspections	953	918	988
# Samples	3,257-total 1,226-pet 334 Unofficial	3,322-total 1,513-pet 233 Unofficial	3,277-total 1,019-pet 523 Unofficial
# Lab analyses	>33,000	>33,000	>33,000
Samples passed	79%	75%	76%
Components passed	96%	95%	95%
# Products registered	23,846 (3,644 new)	23,035 (3,679 new)	22,995 (4,365 new)

Fertilizer Program

Fertilizer sampling and analyses were down slightly in 2020 compared to the previous two years but not significantly. As with feed, our inspectors will sample bulk or large package items and purchase small package items such as those found in box stores.

Fertilizer Program			
Year	2018	2019	2020
# Inspections	1,112	1,300	1,150
# Official samples	2,703	2,692	2,460
# Lab analyses	7,511	7,205	6,584
% Samples passed	92.3	92.6	92.0
# Products registered	5,600	5,900	6,170
Firms selling in KY	429	475	458
Licensed custom blenders	178	182	178

Seed Program

Regulatory Services has the only certified seed testing facility in Kentucky. This laboratory serves as both a regulatory and service laboratory. It handles all official samples collected by inspectors and provides service testing for seed producers, dealers, retailers, research projects (including endophyte fescue testing) and homeowners for a fee. In addition, Kentucky residents by law are allowed one free seed sample per year. More than 90% of the service samples accepted into the laboratory were submitted by Kentucky firms or individuals.

Inspectors will sample crop, pasture, flower, and vegetable seeds. In addition, in 2020 we started purchasing seed from online retailers.

Continued on page 4

Seed Regulatory Program			
Year	2018	2019	2020
# Inspections	1,009	1,078	1,050
# Official samples	1,563	1,738	1,477
Stop sales on samples	215	257	211
Stop sale @ dealer	131	32	13
Registered seed dealers	629	628	673
Reg. non-cert. seed cond.	29	28	30
Permits to label Ag Seed	215	214	253
Permits (veg & flower)	60	59	89

Seed Service Program			
Year	2018	2019	2020
# Service samples	2,262	2,515	2,130
# Research samples	69	60	84
#Endophyte fescue samples	233	274	204
# Kentucky free samples	54	61	44

Milk Program

The mission of the milk regulatory program is to ensure raw farm milk produced and marketed in Kentucky is bought and sold using accurate weights and tests. The program's primary function is to monitor milk handling systems from the time a producer's milk is sampled and weighed, through delivery and laboratory testing, until producer payments are calculated. The program provides support to the producers and processors of Kentucky's dairy industry. Industry participants are trained, licensed, and subsequently monitored to maintain compliance with the law.

In addition to regulatory functions, the milk program cooperates with other agencies in educational projects to provide a variety of services to Kentucky dairy producers, processors, and allied industries. Our laboratory provides milk testing services to support research projects within the College. The milk program also operates a laboratory that is available for Kentucky producer, processor and handler service testing and cooperates with both USDA and FDA to provide analytical services when the need arises. The main effect Covid had on this program was a reduction in training of personnel.

Milk Program			
Year	2018	2019	2020
Licenses issued	449	509	497
Milk handler personnel trained	30	55	18
Audits	20	18	19
Lab inspections	28	33	27
Sampler/weigher inspections	304	287	276
Milk samples analyzed	1,883	1,454	1,316

The purpose of sharing these tables is two-fold. One is to document the amount of work the Division of Regulatory Services does to protect consumers and keep a level playing field for agribusinesses. We are proud of what we do and too often do not share those efforts with others. Secondly, to demonstrate that even with all the setbacks we dealt with in 2020 due to the coronavirus pandemic we still managed to have similar performance data with previous years. I am proud of all our employees for the efforts they put forth in 2020 under challenging circumstances.

These tables are only short summaries of the work done by each program. The feed, fertilizer, and seed programs all produce annual reports that present the results for each company tested. These reports are available on our website at www.rs.uky.edu.

*Dr. Darrell D. Johnson,
Executive Director*

Seed Lab Update and Endophyte Testing

Spring is well underway in the bluegrass, along with our busy season here in the seed laboratory. As the pandemic continues, and hopefully begins to ebb; we remain dedicated as ever to providing timely results to the seedsmen across the commonwealth and elsewhere. We have learned a lot over the last year about safety precautions, zoom meetings and working remotely. However, I am very happy to notice, as I am sure all of you are, a slow return to a sense of normalcy in our world.

Here in the seed lab the spring rush more closely resembles that of years prior to 2020 with an increased number of samples coming in as farmers and businesses across the country begin to get back on track. As we make the return to normal and testing levels increase, I wanted to remind everyone of our ability to analyze tall fescue for Endophyte as it seems to be one of the lesser-known tests provided by the seed lab.

For several years, the seed lab has provided tall fescue Endophyte testing for its customers. We have the capability to analyze both live tillers and seeds, though the vast majority of our work is testing tillers. Both live tillers and seeds are analyzed by our lab using kits supplied by Agrinostics Ltd. in Watkinsville, Ga. It is also important to note that the test we provide will indicate whether the endophyte fungus is present, it will not identify individual alkaloids.

There are a few issues that I routinely see with regards to samples submitted for endophyte analysis and would like to offer some helpful tips. First and foremost, the proper shipment of samples for analysis is paramount. Tillers, when sent, must remain frozen to ensure the tissues do not begin to degrade, but often samples will arrive to the lab partially or completely thawed. To avoid this, please use frozen ice packs and coolers and ship your samples overnight early in the week or hand deliver as even the best packed coolers will not keep samples frozen over a weekend. Secondly and

equally as important as proper shipment, is the condition of the tillers at the time of collection. If the stems are in their dormant state, several of the outer tissue layers are dead and the chance of a false negative result greatly increases, as only living tissues will interact with the chemicals during analysis. These partially dormant/dead tillers also pose a real challenge for sample preparation as they fall apart readily and do not allow for proper processing.

As a reminder, the Regulatory webpage contains a detailed “how-to” on the proper collection of tillers for analysis. I would encourage everyone to view these materials and other submittal information before collecting samples, especially if it has been a few years since you have submitted a sample to the seed lab.

You will notice upon visiting our website that we have included additional information on the Endophyte submittal form. This includes more in-depth information on Endophyte testing and our suggestions on the most optimal collection times for live tillers.

*Jonathan Collett,
Seed Lab Supervisor*

Next Gen Fertilizer Challenges

A joint EPA-USDA partnership and collaboration with The Fertilizer Institute (TFI), the International Fertilizer Development Center (IFDC), The Nature Conservancy (TNC), and the National Corn Growers Association (NCGA) established two challenges to review Enhanced Efficiency Fertilizers and how they may reduce some environmental impacts from row crop agriculture but to still maintain or increase crop yields. An Enhanced Efficiency Fertilizer as defined by the Association of American Plant Food Control Officials (AAPFCO) describes fertilizer products with characteristics that allow increased nutrient availability and reduce potential of nutrient losses to the environment e.g., gaseous losses, leaching or runoff when compared to an appropriate reference product. *(continued on page 6)*

The first stage of the “EEFs: Environmental and Agronomic Challenge” included a review and selection of the following companies and their products to move to the second stage of greenhouse trials starting this spring.

AgroLiquid: Pro-Germinator
CHS Agronomy: Trivar
Corteva Agriscience: Optinyte
EuroChem Agro: ENTEC
Harrell’s: POLYON
Koch Company Services: CENTURO
Koch Company Services: SUPERU
MicroSource: Hi-Test
Nutrien: ESN
Pursell Agri-Tech: PurYield
Renuvix: Renuvix CRFs
SABIC: BCRU
The Andersons: Struvite DG
Timac Agro USA: Duo Maxx
Timac Agro USA: Top-Phos
Verdesian Life Sciences: AVAIL

The third stage will include field trials in 2022 pending funding.

The second challenge “Next Gen Fertilizer Innovations Challenge” will review EEFs which are not ready for market or other novel technologies. An expert panel will review and recommend winners which may be rewarded a monetary award and/or an invitation to a showcasing event this fall or winter. Additional information on these challenges can be found at <https://www.epa.gov/innovation/next-gen-fertilizer-challenges#Goal>

*Steve McMurry,
Director of Fertilizer and Seed Programs*

Feed Sample Reports: Responding to Sample Violations

The statute that grants authority for our inspectors to collect feed samples at Kentucky distributors (KRS 250.581) also requires that we send the results of official samples to “*the person named on the label and to the purchaser*”. Our policy continues to be to send a copy of the report to both the guarantor and the distributor of the product.

Kentucky law and regulations are used to determine that a sample failed to meet any label guarantee. The laws and regulation listed below are referenced in the Manufacturer’s Report on Investigation of Label Violation that accompanies all reports with one or more violations.

12 KAR 2:021, Section 10. The guaranteed analyses that appear upon the label of a commercial feed shall adequately inform the consumer of the actual nutrient content of a product. The Division of Regulatory Services shall use the 2018 Table of Kentucky Analytical Variations to determine those analytes that fall outside of acceptable ranges.

KRS 250.531: A commercial feed shall be deemed to be misbranded: 1. If its labeling is false or misleading in any particular.

KRS 250.591 1. When the director has reasonable cause to believe any lot of commercial feed is being distributed in violation of any of the provisions of KRS 250.491 to 250.631 or of any of the prescribed administrative regulations under KRS 250.491 to 250.631, he may issue and enforce a written or printed "withdrawal from distribution" order, warning the distributor not to dispose of the lot of commercial feed in any manner until written permission is given by the director or the court.

When a product sampled fails to meet any of the label guarantees, the manufacturer or guarantor is asked to investigate and report back to the Feed Director. I strongly encourage all guarantors to take the

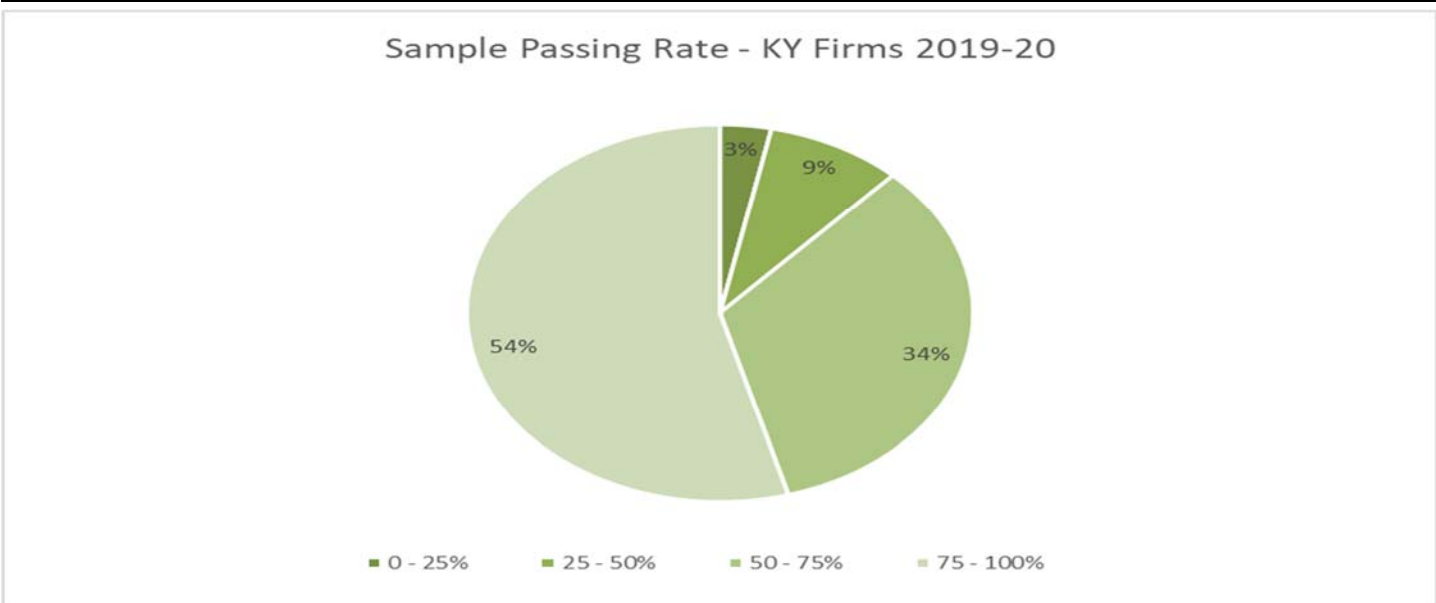
time to fill out the form and make the needed corrections to the formula, the label, or both. We are also available to assist firms that want to make more consistent products that meet guarantees. Many times, the issue is more related to mistakes in labeling than a formulation error. All responses are reviewed and the inspector that collected the sample receives a copy of this response.

I have tracked responses to violations for the last several years and the overall response rate has dropped from 50% in 2016 to 35% in 2020. I'm not satisfied with getting responses on 3-4 samples for every 10 violative samples. We now use email to send the majority of sample reports and are explor-

ing ways to make it more convenient for firms to respond.

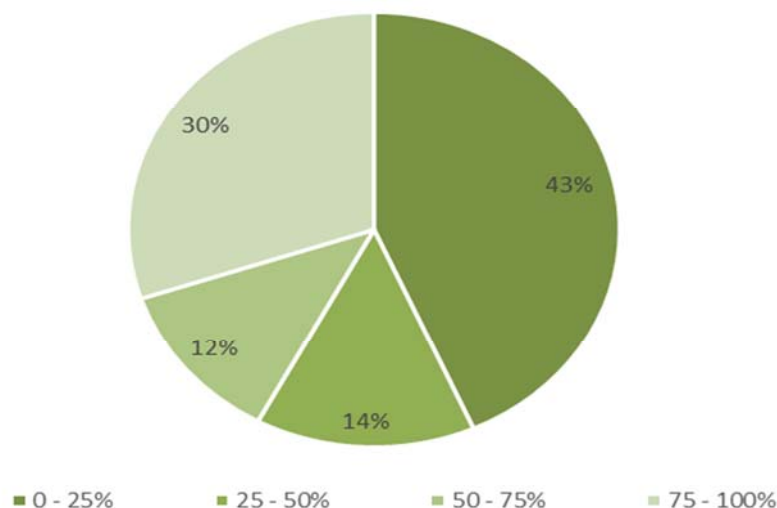
The table below summarizes both sample pass rate and violation response rate for KY firms for the last two years (2019-2020). The 92 firms with a minimum of 4 samples collected over the 2-year period represent 96% of samples with KY guarantors during this time. The average sample pass rate of 72% is similar to previous years. More than 50% of our firms had a pass rate of 75% or greater. The average violation response rate of 40% could certainly be better. Of particular concern are the 32 KY firms that have not responded to a single request for investigation in the past two years.

Feed Sample Compliance and Guarantor Response to Violations						
Kentucky Guarantors and Manufacturers: 2019-20						
Minimum of 4 samples						
# Firms	Samples Total	Samples Passed	Samples Violative	Responses	Avg Samples Passed %	Avg Violation Responses %
92	2288	1709	579	215	72%	40%
# firms with:	100% pass rate		9	9		9 KY firms
	0% pass rate		1	1		1 KY firms
	100% response rate		14	14		14 KY firms
	0% response rate		32	32		32 KY firms



Continued on page 8

Violation Response Rate - KY Firms 2019-20



We have the statutory authority to withdraw from distribution any product not meeting any guarantee on the label. A withdrawal from distribution notice requires a response from the guarantor and has consequences for the distributor. In the past few years, we have not exercised this option on a routine basis. Beginning this summer, our feed program will begin utilizing the withdrawal from distribution option more frequently. For select analytes, we will issue withdrawals from distribution for all sample violations. These include non-protein nitrogen, salt, copper, selenium, and all medications. For all other

analytes, the feed program will continue to use discretion in issuing withdrawals from distribution when samples fail. The decision-making process will include the firm's compliance history with the product or similar products.

The goals of these adjustments in our feed sampling program are improving sample compliance rate and overall responsiveness of firms to sample violations.

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

Plant Tissue Analysis at Princeton Soils Lab

The Soils lab at the UK Research and Education Center at Princeton will start offering a new service of plant tissue testing on May 20th. Soil testing is very important to determine adequate level of nutrients and pH in crop production. Plant tissue testing can be used in addition to soil testing as an investigative tool. Results from plant analysis can help determine what may be affecting plant nutrient uptake in problem areas of a field.

Sampling plants for testing is more involved than soil testing. Differences in nutrient uptake in different parts of the plants and at different stages of

growth means careful attention has to be applied to sampling the correct portions of the plant. A good illustrative guide for sampling plant tissue from crops commonly grown in Kentucky is available in the UK Extension publication entitled "Sampling Plant Tissue for Nutrient Analysis, AGR-92".

If interested in submitting a plant sample for testing, the procedure is similar to submitting a soil sample. Your local County Extension Office will have information on sample submission. Sample submittal forms will be available at www.rs.uky.edu/soil/. Sample bags will be available at County Extension Offices or a regular brown paper bag can be used. Expect approximately a 2 week turnaround

time for reports to be sent to the County Extension Office. The cost for a plant tissue test will be \$16.00. Any questions on this new test can be directed to Amanda Martin who is the Princeton Soils Lab Supervisor (amanda.martin2@uky.edu; 859-562-1325).

*Dr. Frank Sikora,
Director of Labs and Soils*

Soil Testing Laboratory 2020

Soil testing provides agricultural producers, homeowners, greenhouse operators, and others with valuable information on the fertility status of their soils or greenhouse media. The laboratory works in close partnership with the University Cooperative Extension Service to provide laboratory results along with lime and fertilizer recommendations. The philosophy behind our recommendations is to optimize economic benefit to the producer by maximizing crop yield, minimizing input costs, and maintaining fertile soil. We also offer analyses of animal wastes and nutrient solutions used to supply nutrients to agronomic and horticultural crops.

The laboratory supported research programs throughout the UK College of Agriculture with 9,359 samples tested. Our analyses help support research that improves on information to benefit crop production and environmental stewardship.

The number of samples analyzed in 2020 with the percent change from 2019 is shown in the table below.

Sample Type	Number	% change
Agriculture	25,235	-13
Home lawn and garden	8,285	0
Commercial horticulture	861	+5
Greenhouse media	76	-25
Animal waste	191	-71
Nutrient solution	87	+5
Soil nitrate	18	-68
Research samples	9,359	+9
Agricultural Lime	136	-1
TOTAL	44,248	-7

Kentucky Department of Agriculture partnerships

Partnerships were continued with Kentucky Department of Agriculture for testing agricultural limestone and hemp. Testing agricultural limestone began in the fall of 2016 and was continued through 2020. Hemp testing began in 2017 and continued through 2020.

Agricultural limestone was tested for relative neutralizing value which is important for producers to assess limestone quality from a quarry. The relative neutralizing value is used in soil test reports generated from the Division Soil Test Laboratory to supply tailored limestone recommendations based on the quarry the lime is coming from. Sixty-two quarries were sampled and tested in Spring 2020 and 69 in Fall 2020. Lime results are provided at www.rs.uky.edu/soil/technical_info/

Hemp was tested for the psychoactive compound, THC, to verify the concentration was below an allowed level of 0.399%. The Kentucky Department of Agriculture began using our lab as well as the Veterinary Diagnostic Lab at Murray State University for testing hemp in their regulatory program. We tested 1,252 samples from KDA. 202 samples were tested to support research at UK.

In support of assessing and improving hemp analysis, a proficiency testing program was initiated in fall 2018 and continued in fall of 2020. Application fee in 2020 was \$600 per lab. Seventy-eight labs were enrolled in the program. Extra samples were also available for sale to laboratories.

As with our other laboratories, the soil testing laboratory at the UK Division of Regulatory Services still functioned at a high level throughout the pandemic. Please visit our website for more information or assistance. www.rs.uky.edu/soil/

*Dr. Frank Sikora,
Director of Labs and Soils*

FDA Extends Registration Period for Unique Facility Identifier Requirement for Food Facility Registration

The University of Kentucky Division of Regulatory Services is not the FDA nor is it required to notify, aid, or assist firms with FDA registration processes; however, being Kentucky's feed control officials and as a part of the University, we view it as educational and informational to inform KY firms of crucial federal information.

Last year the feed program sent notices to inform firms of the biennial registration renewal period, identified firms as potentially able to utilize PC Animal Food Rule Exemptions/Modified Requirements and thus able to attest to their businesses' status as a qualified facility. Just last week, the division again sent out follow-up letters informing firms if the program was able to confirm facility registrations and facility attestations within FDA's FURLS system. Those identified firms received one of three different letters. The first letter informed them that we were able to confirm their facility registration and attestation. The second letter was a confirmation of facility registration but a failure to find record of their facility attestation. The third letter stated that we were not able to confirm facility registration nor were we able to confirm attestation.

The extension...

Animal food facilities are required to renew their registration and file self-attestation forms every other year, during the period beginning on October 1 and ending on December 31 of each even-number year.

The latest biennial registration renewal period ended on December 31, 2020; **however**, the FDA has extended the time period to obtain and submit a unique facility identifier until December 31, 2022.

Self-attestation indicates that your firm is compliant with Good Manufacturing Practices (GMPs) and **does not** need Preventative Controls. By self-attesting, firms may limit the scope of FDA inspection to GMPs and potentially avoid additional lengthy inspections.

Please see the below links for additional information:

<https://www.fda.gov/food/cfsan-constituent-updates/fda-extends-flexibility-unique-facility-identifier-requirement-food-facility-registration-through>

Site to Facility Registration:
<https://www.access.fda.gov/>

Directions & a step by step explanation of the registration process:

<https://www.fda.gov/food/online-registration-food-facilities/food-facility-registration-user-guide-step-step-instructions>

Directions for self-attestation:
<https://www.fda.gov/media/123994/download>

Q&A on facility registration:
www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-facility-registration-seventh-edition

*Jennifer Combs
Regulatory Associate/AFRPS Specialist*

Upcoming Meetings

American Association of Seed Control Officials (AASCO)

Annual Virtual Meeting-July 13-14, 2021
www.seedcontrol.org/meetings.html

Association of American Plant Food Control Officials (AAPFCO)

Annual Meeting-TBD
www.aapfco.org/meetings.html

Association of American Feed Control Officials (AAFCO)

Annual Meeting-August 2-4
www.aafco.org/Meetings

Personnel Notes



We are pleased to welcome Carolyn Goodrich as the newest employee of Regulatory Services. Carolyn started work as an Administrative Support Associate on March 15, 2021. She replaces Laura Sidwell who took a job at UK Healthcare. She deals primarily with the budget, travel, and accounts payable.

Carolyn is a native of Iowa and moved to Lexington from California in 2019. She previously worked 23 years as an Assistant to the Office Manager/Board Secretary for the San Luis Obispo County Integrated Waste Management Authority. She also worked as a Dental Laboratory Technician for the United States Army.

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

Regulatory Services News is delivered electronically each quarter. Please feel free to share this publication with others in your organization and if they would like to subscribe, they may do so on the front page of our website at www.rs.uky.edu.



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