Regulatory Services News

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Director's Digest

Looking forward and looking back

January 1, 2020 represented not only the start of a new year but also the start of a new decade. Many publications are offering their predictions about what will happen in the '20's. At my age, I tend to be trepidatious about what the future offers and nostalgic about the past. I thought it might be interesting to look back through previous editions of Regulatory Services News and see what was being discussed at the start of previous decades.

1970

The February 1970 issue featured the following note to dealers from the "Tobacco Talk" newsletter put out by tobacco specialist Ira Massie:

Regulatory Services at the University of Kentucky will not register fertilizer-pesticide mixtures in 1970. Notice has already been given to all fertilizer dealers in Kentucky.

The University of Kentucky Entomology Department will not recommend the use of the compounds, "chlorinated hydrocarbons," this year.

The United States Department of Agriculture has banned the use of DDT on all tobacco grown in 1970.

Tobacco industry leaders have also been concerned with pesticide levels because of their threat to the acceptance of some export leaf. West Germany already has plans to reduce its level of acceptance to one-tenth part DDT per million in 1973. Other large importers of American leaf are indicating they will reduce tolerance levels in the future.

Evidence is in that use of DDT and pesticide-fertilizer mixtures are hurting the industry. Tobacco is grown by 126,000 farm families in Kentucky, and it accounts for about 40 percent of the state's agricultural income. Why would anyone threaten this industry? Although it is probably unintentional, they do this by using pesticides which may reduce or hurt production and may be unaccepted as foreign imports.

It's been a long time since I had thought about DDT and since tobacco was that big a contributor to the Kentucky economy.

1980

The January newsletter was celebrating the fact that the Kentucky Fertilizer law was 100 years old as covered by Newsletter editor Dr. Dave Terry:

"An Act to prevent fraud in the manufacture and sale of commercial fertilizers in this Commonwealth."

The above statement serves as the preface to the first law enacted in Kentucky to regulate the **manufacture** and **sale** of commercial fertilizers. This law was approved by the General Assembly of the

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Commonwealth of Kentucky on April 22, 1880 and became effective on May 15, 1880.

This was approximately five and a half years before the establishment of the Kentucky Agricultural Experiment Station in September 1885, and seven years before the U. S. Congress passed the Hatch Act in March 1887.

In the September issue, Dr. Eli Miller reported on efforts to prepare for the implementation of a new program to regulate manufacturers of medicated feed. It is interesting to note why firms failed pre-approval inspections:

The Division of Regulatory Services has contracted with FDA to conduct 120 pre-approval inspections of Kentucky mills by July 1981. Seven inspections were completed during June and 16 in July. A summary of these 23 inspections indicated that 5 firms passed, 14 firms did not pass, and 4 firms had previously discontinued manufacture of medicated feed. Only 5 of the 19 firms inspected that presently manufacture medicated feed were determined to qualify under the new program to use "high risk" drugs. Nationally, an FDA review of 300 inspections indicated a 57% failure rate.

Why are firms failing the pre-approval inspection? It should be recognized that a directed inspection examines eight critical points of GMP regulations. Failure to meet any of these eight points results in the firm failing the directed inspection. The critical eight points are:

1. No record that drug scales have been calibrated and checked for accuracy within the last year.
2. No drug assays have been performed in the past 12 months.
3. Failure to maintain a drug inventory record.
4. Firm has no provisions for routinely cleaning and flushing its equipment, or sequential production system, or other equally effective procedures to avoid unsafe contamination.
5. Label controls are not adequate to prevent mix-ups in receipt, handling, and storage.
6. Ten percent or more of assays performed are out of specified ranges.
7. The firm is totally without any master or batch records.
8. Batch records have gross miscalculations which may lead to significant super- or sub-potency.

A review of the 14 inspection reports for firms that did not pass indicates that lack of drug assays and uncalibrated drug scales accounted for 12 of the 14 failures. . . . . My preliminary judgement is that few firms will qualify to purchase and mix "high risk drugs and most qualified firms will be the larger mill operations. Qualification is not determined by size of the operation but by management's commitment to employ good manufacturing procedures in the daily production of medicated feed.

1990

The Spring 1990 newsletter primarily celebrated the move into the new $3.5 million Regulatory Services Building which was dedicated to Bruce Poundstone who administered the Division for 25 years. This means we have been in our current facility for 30 years. I particularly liked the comments about the history and purpose of our Division.

For more than a century, the Division of Regulatory Services has guarded the safety and quality of many agricultural products. The division, a part of the Agricultural Experiment Station in the college of Agriculture, administers the state fertilizer, seed, feed and creamery license laws. It regulates the sale of fertilizer, seed, pet and livestock feeds and raw milk and operates service laboratories for seed and soil samples.

Regulatory officials inspect production, wholesale and retail facilities. They take samples to test of inferior or unsafe products and to confirm that ingredients match labels.

Also noted in this edition was the amended feed law that was signed by Governor Wallace Wilkinson and went into effect on July 1, 1990. This was the first change in the feed law since 1972. The 1990 amendments revised inspection fees, added three new adulteration provisions and broadened the definition of feed labeling. The feed law has not been changed since then, but regulations were revised in 2018.

2000

Most of us remember the fear that changing from 1999 to 2000 generated as to whether all our computers would shut down at midnight on 12-31-99. To my knowledge, there were no major issues.

For Regulatory Services, the 2000 General Assembly modernized the Kentucky Creamery License Law to improve service to Kentucky's dairy industry. This law also set up the Milk Advisory Board which meets each spring to provide us input on our milk program. The revised law took effect on January 1, 2001.

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Director's Digest, continued

This was also the year that the maximum chlorine in tobacco fertilizer regulation was adopted. As noted by Dr. Terry in Regulatory Services News:

Briefly, the proposed regulation requires that all tobacco fertilizer be labeled to show:

(1) The fertilizer is for tobacco.

(2) A maximum chlorine guarantee of not more than 50 pounds of chlorine per acre in the following format:

Chlorine (Cl), Maximum . . . . . 50 lb./acre, and

(3) Specific directions for use to include a maximum application rate in pounds or tons per acre so that the amount of chlorine applied will not exceed 50 pounds per acre.

Coincidentally, this chlorine regulation is being reevaluated as we work to revise our fertilizer regulations in 2020.

2010

The decade we just completed has been a very active one for all in agribusiness. Below are some of the many factors we have faced in this decade that change what we do on a daily basis:

- **Food Safety Modernization Act**-This has had a major impact on both those of you in the feed business and those of us in Regulatory Services. We have tried to work with you in complying with these rules and hope we have been helpful.
- **E-commerce** - This decade has seen tremendous growth in online purchases of everything including feed, seed, and fertilizer. It has certainly been a challenge for those of you with store fronts but also a challenge for us on how to regulate.
- **Electronic communications** – We have seen a tremendous change in the last ten years in the use of email versus snail mail. We have been slow to adapt in Regulatory Services but are trying to move more in this direction.
- **GMO's** – We've certainly seen a large growth in the use of GMO's and also a lot of angst against using them.
- **Pet Food** – There has been a large growth in pet food and pet treat sales over the past ten years. This has definitely affected our sampling plans.
- **New Products**- Biostimulants in the fertilizer world, hemp/cbd products in the feed world, artificial milk and meat products in the food world, and coated and/or diluted products in the seed world are among just a few of the new products that regulations and analytical procedures are still being developed for.
- **Consumer Activism** - Consumers are king and they are wanting to know more and more about where their food products come from. Dealing with their demands successfully will be a major determinant to who is still in business at the end of the next decade.

These are just a few of the changes we have seen in the agribusiness world in the past fifty years and we know there are many more to come during this next decade. Please let us know what we can do to help you deal with the regulations you face.

Dr. Darrell Johnson,
Executive Director

Fertilizer Heavy Metals Analysis for 2018-2019 Samples

Soils and fertilizer source materials naturally contain heavy metals. Federal, state and industry sponsored risk assessments demonstrate that metals in fertilizer generally do not pose harm to human health or the environment. Heavy metals can be introduced into fertilizer thru the process of recycling industrial wastes or other source materials. As long as the recycled waste materials do not exceed the treatment standards specified as waste (40 CFR 266.20) they can be designated as a beneficial recycling material and fertilizer source. The Association of American Plant Food Control Officials (AAPFCO) has established that phosphate and/or micronutrient fertilizers are adulterated when they contain metals in amounts greater than established limits. These limits are based on the amount of phosphate and/or micronutrient guarantees. The Division of Regulatory Services routinely screens for heavy metals. Our office screens for the following: Arsenic (As), Cadmium (Cd), Cobalt (Co), Molybdenum (Mo), Nickel (Ni), Lead (Pb), Selenium (Se), and Zinc (Zn).

The tables on the next two pages show the results we found for heavy metal content of several mixed fertilizers as well as fertilizer materials used in the production of custom mixes. Our analysis on fertilizer materials from 2018-2019 did not find any values above established limits.

Table 1. Heavy Metals Analytical Results from the 2018-2019 Samples (Arsenic to Molybdenum)
All Results in PPM (Columns starting with L depict maximum allowable limit)
A Missing Value Means That the Concentration of the Element was Below Detection Limits

Grade	As	LAs	Cd	LCd	Co	LCo	Mo	LMo
12-40-0	9	1120	19	830	2	22280	7	3000
12-40-0	7	1232	30	913	2	24508	5	3300
18-46-0	9	598	29	460	2	6256	6	1932
24-10-10		130	8	100		1360	1	420
16-1-0	4	2240		1660	2	44560	3	6000
6-12-18	2	1719	3	1274	1	34200	3	4605
24-8-16		104		80		1088	5	336
16-1-0	2	2240		1660	3	44560		6000
11-52-0	10	676	2	520	3	7072	1	2184
15%B	19	1680		1245		33420	7	4500
0-46-0	6	598	24	460	1	6256	16	1932
36% Mg	4	4704	11	3486	13	93576	24	12600
10%B	20	2968		2200	6	59042	4	7950
10-8-6	3	2010	5	1490	4	39993	2	5385
18-46-0	17	598	28	460	2	6256	7	1932
15-15-15	3	195	3	150	1	2040	2	630
0-46-0	6	598	23	460		6256	17	1932
15% B	78	1680		1245	1	33420	6	4500
18-46-0	4	598	8	460		6256	1	1932
18-46-0	6	598	35	460	2	6256	3	1932
18-46-0	12	598	5	460	3	6256	12	1932
4-25-0	2	2800	7	2075	27	55700		7500
20-20-20		260		200		2720	45	840
18-46-0	13	598	35	460	1	6256	4	1932
11-52-0	8	676	42	520	2	7072	5	2184
0-46-0	9	598	22	460	1	6256	2	1932
3-17-0	14	221		170		2312		714
20% Zn	4	3808	4	2822	12	75752	14	10200
36% Zn	11	5040	16	3735	11	100260	30	13500
10-20-20	3	260		200	1	2720	1	840
1-0-1	3	3696	5	2739	58	73524	2	9900
19-19-19	4	247		190	1	2584		798
19-19-19	3	247	7	190	1	2584	2	798
18-46-0	6	598		460	1	6256	1	1932
18-46-0	13	598	28	460	1	6256	5	1932
0-0-22		3696		2739		73524		9900
19-14-19	3	280	3	208	1	5570	1	750
18-18-21	1	234		180		2448		756
10-10-10	2	130	1	100	1	1360	8	420

Table 2. Heavy Metals Analytical Results from the 2018-2019 Samples (Nickel to Zinc)
All Results in PPM (Columns starting with L depict maximum allowable limit)
A Missing Value Means That the Concentration of the Element was Below Detection Limits

Grade	Ni	LNi	Pb	LPb	Se	LSe	Zn	LZn
12-40-0	12	19000	7	4630	4	1800	242	29000
12-40-0	13	20900	1	5093	5	1980		
18-46-0	13	11500	6	2806		1196	124	19320
24-10-10	3	2500		610		260	95	4200
16-1-0	8	38000	10	9260	8	3600	187	58000
6-12-18	8	29165	9	7107		2763	1257	44515
24-8-16	2	2000	2	488	5	208	558	3360
16-1-0	9	38000	11	9260	1	3600	194	58000
11-52-0	7	13000	2	3172		1352	63	21840
15%B	1	28500	7	6945		2700	10	43500
0-46-0	41	11500	1	2806	4	1196	512	19320
36% Mg	122	79800	45	19446	9	7560	8790	121800
10%B	19	50350	20	12270	5	4770	1761	76850
10-8-6	33	34105	16	8311		3231	655	52055
18-46-0	35	11500	3	2806		1196	239	19320
15-15-15	6	3750	1	915		390	46	6300
0-46-0	40	11500	1	2806	4	1196	519	19320
15% B	9	28500	8	6945		2700	13	43500
18-46-0	10	11500		2806		1196	78	19320
18-46-0	11	11500	4	2806		1196	143	19320
18-46-0	15	11500	7	2806		1196	85	19320
4-25-0	23	47500	43	11575	38	4500		
20-20-20	0	5000	2	1220	1	520	621	8400
18-46-0	31	11500	2	2806		1196	266	19320
11-52-0	14	13000	7	3172		1352	132	21840
0-46-0	24	11500	3	2806		1196	333	19320
3-17-0		4250	2	1037		442	4315	7140
20% Zn	157	64600	258	15742	7	6120		
36% Zn	208	85500	105	20835	12	8100		
10-20-20	9	5000	2	1220		520	414	8400
1-0-1	90	62700	249	15279		5940	88	95700
19-19-19	2	4750	2	1159		494	29	7980
19-19-19	4	4750	2	1159		494	46	7980
18-46-0	4	11500	3	2806		1196	12	19320
18-46-0	32	11500	2	2806		1196	282	19320
0-0-22	39	62700		15279		5940	22	95700
19-14-19	5	4750	2	1158	1	450	54	7250
18-18-21	3	4500	1	1098	1	468	544	7560
10-10-10	42	2500	5	610		260	16	4200

No LZn value if Zn is guaranteed.
No limit values for potash samples

Steve McMurry
Director of Fertilizer and Seed Programs

A Review of Three Years of Inspections under Food Safety Modernization Act Regulations

With 3 years of inspections under our belt, it is an appropriate time to share some of our experiences with inspections under The Food Safety Modernization Act (FSMA). All facilities, regardless of size, that manufacture, process, pack, or hold animal food need to comply with Good Manufacturing Practices (GMP's) regulations covered under 21 CFR Part 507 Subpart B. The other half of FSMA regulations involve Hazard Analysis and Risk-Based Preventative Controls (PC's) under 21 CFR Part 507 Subpart C. The largest manufacturers are already dealing with PC's and PC inspections but Kentucky is focusing on cGMP education and compliance first. Our inspectors are receiving training to conduct PC inspections and we will be doing a limited number of these inspections in the fall of 2020 (more on this at the end of this article). This article will discuss inspectors' experiences in inspecting KY feed mills in the past 3 years and hopefully, provide useful information to feed mill operators concerning where to focus improvement efforts.

The heart of the cGMP inspection for compliance with 21 CFR Part 507 Subpart B is a review of each of the 8 sections of the regulation:

1. Personnel
2. Plant and grounds
3. Sanitation
4. Water supply and plumbing
5. Equipment and utensils
6. Plant operations
7. Holding and distribution
8. Holding and distribution of human food by-products for use as animal food

In addition to Subpart B, a cGMP inspection will also cover Subpart A which outlines qualifications of all individuals involved in production and distribution of animal feed.

To date, our inspectors have conducted a total of 51 cGMP inspections at Kentucky firms. These inspections represent over 25% of the manufacturing facilities and include feed mills of all sizes and manufacturers of both ingredients and pet food. During each inspection, our inspectors note any areas where the facility is not in compliance with regulations. These are listed as items for discussion with management in the inspection report. About 40% of these inspections (20) did not result in any discussion items. For the other 31 inspections, we had a total of 134 discussion items (average of 4.3 per inspection).

The two regulation areas with the greatest number of discussion items were Plants and Grounds (37 items) and Plant Operations (35 items). Plants and Grounds (CFR 507.17) covers the grounds around the facility and the building itself. Specific discussion items that fell under this regulation have included holes in building walls and roofs, poor drainage and standing water around facility, and conditions near building that could attract or harbor pests (trash, weeds, etc.)

Plant Operations (CFR 507.25) is quite extensive and covers all the individual operations involved with manufacturing and packaging feed to ensure a safe product is produced. Under the areas included in this regulation, typical discussion items have mentioned missing covers or screens for pits and augers, lack of shatter-resistant lights, and failure to properly label ingredients and rework feed.

The other regulation areas in Subpart B with discussion items were Sanitation (26 items), Holding and Distributing (14 items), and Equipment and Utensils (2 items). Sanitation (CFR 507.17) covers the grounds around the facility and the building itself and includes language regarding the storage of non-feed materials in the plant area. Our inspectors have reported old feed spillages around mixers and grates, containers of paint, oil, and chemicals in feed production areas, and debris and trash on feed mill floors.

Holding and Distribution (CFR 507.27) regulations focus on storing feed for distribution in such a way to protect it from contamination and minimize deterioration. Discussion items related to this area have included comments on the cleanliness of totes and bulk trucks and the failure to have a recall plan.

Under Qualifications of Individuals who Manufacture, Process, Pack or Hold Animal Food (507.4) are the regulations which ensure that everyone knows their job or jobs. The discussion items in this area (20) all mentioned the training program and records documenting training.

These initial inspections for compliance with GMP's under Part 507 have focused on education. We did not expect that all facilities would meet all these requirements. The flexibility that FDA built into these GMP regulations does allow application to a variety of animal feed production facility types and allows the management to meet the requirements in different ways. As our inspectors follow up on the problem areas, they will be looking for progress towards achieving full compliance.

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For the firms that will be eligible for the Preventative Controls (PC) inspections under 21 CFR Part 507 Subpart C, our inspectors will be conducting the first inspections this fall. FDA's general philosophy regarding inspections has shifted to covering more regulations with fewer inspections. One downside of this is that it means more time necessary per inspection visit. We have found over the last 3 years that the combination of a Part 225 medicated feed inspection and a Part 507 cGMP inspection can take more than one day even with 2 experienced inspectors. Adding a PC inspection could easily result in another ½ day of inspection time.

Dr. Alan Harrison,
Director Feed and Milk Programs

Biostimulant Report to the President and United States Congress

In early January the United States Department of Agriculture (USDA) in consultation with the Environmental Protection Agency (EPA) reported to the President of the United States and United States Congress on plant biostimulants. Within the 2018 Farm Bill, it directed the Secretary of Agriculture to submit a report to congress to address biostimulants and create recommendations for a regulatory program for biostimulant products. Within this report a definition of biostimulant is proposed:

"a substance or micro-organism that, when applied to seeds, plants, or the rhizosphere, stimulates natural processes to enhance or benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, or crop quality and yield."

The participants which helped create several options for a regulatory framework included USDA, EPA, Food and Drug Administration (FDA), Association of American Pesticide Control Officials (AAPCO), Association of American Plant Food Control Officials (AAPFCO), National Association of State Departments of Agriculture (NASDA), American Seed Trade Association, Biological Products Industry Alliance, United States Biostimulant Coalition, Biotechnology Innovation Organization, Humic Products Trade Association, the Fertilizer Institute, and the Phytobiomes Alliance. After several meetings and time for comment, the following options were reported:

1. Harmonize existing State and Federal programs that regulate fertilizers and soil inoculants. States would need to adapt existing guidance for beneficial substances and develop labeling options.
2. NASDA facilitates a State by State approach and coordinates efforts with AAPFCO to create a model bill of State regulations for beneficial substances, including plant biostimulants.
3. Similar to option 2 except USDA would facilitate the process about a model bill that States would use to enact legislation.
4. Congress enacts legislation to establish a uniform national definition of "plant biostimulant" and directs the EPA Administrator to amend current pesticide regulations to incorporate the same uniform national definition of "plant biostimulant" and clarify the exclusion of plant biostimulant products from regulations as plant growth regulators under FIFRA.
5. Congress passes a "Plant Biostimulant Act" and grants USDA, EPA, or another Federal agency authority to regulate those plant biostimulant products not currently regulated as pesticides or growth regulators by EPA.
6. A voluntary, fee-for-service non-regulatory approach. A third party verification system confirming products meet certain plant biostimulant standards and criteria.

From the options above it is estimated that a framework could be reached from 2-8 years depending on the path chosen. Options 1 and 6 could take under 3 years and the others from 4 to 8+ years. Whichever path is chosen, the goal is to get industry stakeholders a more efficient, predictable and uniform regulatory process and greater recognition by State and Federal regulators.

Steve McMurry
Director of Fertilizer and Seed Programs

Final Steps to Accreditation to ISO 17025:2017

In this newsletter, we have been discussing the many different areas of quality so that UKDRS labs can become accredited to ISO 17025:2017 for a few years now. We have our quality manual written and implemented. We have written and have in place about 22 quality standard operating procedures (SOPs) and over twice that in accompanying forms. We have trained all of our staff on ISO 17025:2017, our quality manual, our quality SOPs, and our method SOPs. All of our laboratory staff have been evaluated and are documented as competent on the method SOPs that they are authorized to perform. I am so proud of all of our staff for their hard work and dedication to "doing what they say and saying what they do", the unofficial motto for ISO 17025.

We have begun the application process—and it is a process! Our accrediting body (AB) has requested us to complete their documents in addition to our already completed SOPs, forms, and manuals. The first document the AB requires is over 30 pages. It is a checklist where each ISO requirement must be aligned with one of our SOPs. This is not a quick task nor an easy one. Each SOPs that is matched to the ISO requirement must then be uploaded into the AB's secure on-line portal. And, this is just the first requested document!

We also must submit a technical staff matrix for accreditation. This documents where we match up the methods on our scope of accreditation with the analysts who are trained, competent, and authorized to perform the test. And an accurate organizational chart of UKDRS must be submitted.

As a reminder, our Scope of Accreditation are the methods of analysis, in addition to the quality SOPs and quality manual we have adopted to meet ISO 17025. This is broken down by the test, technology, the reference method, (Association of Analytical Chemists (AOAC), ISO, FERN, FDA, etc), or in-house method that has been validated according to ISO 17025 requirements.

Internal audits are performed to verify that UKDRS is meeting the ISO requirements, the AB requirements, and that UKDRS is following our own policies and procedures from our management system and technical requirements—and that these are all documented! Next, management reviews are performed and are documented.

To lessen confusion, one person at UKDRS is designated as the AB authorized representative to assume responsibility for upholding the accreditation requirements and for making them available to staff. This is the person who is given authority from UKDRS to enter into the accreditation agreement with the AB. Once all of these are completed and documents are uploaded into the AB's secure portal, the application is considered complete.

Following this, UKDRS will undergo a pre-assessment. This provides an opportunity for UKDRS to evaluate our preparedness for the initial assessment. A pre-assessment is a practice run for UKDRS to see at first glance how well our management system, quality manual, quality SOPs, training of personnel, and possible any technical requirements meet ISO 17025:2017 and AB requirements. It's an opportunity to identify areas of possible non-compliance before a full assessment is performed. Once UKDRS feels we have successfully addressed any noted items during the pre-assessment, the AB is contacted and the official initial assessment is scheduled.

The official initial accreditation consists of a series of steps. An entry interview between UKDRS laboratory management and the AB assessor begins the day. This is followed by interviews of the technical staff (UKDRS analysts that are trained and authorized to perform the methods that are on the scope of accreditation) by the AB assessor. If a test method on the scope of accreditation is being performed that day, the AB assessor may ask to watch and ask the analyst questions. Equipment and calibration records will be examined. The management system will be audited to ensure that it is fully operational and that it conforms to all sections of ISO 17025, including documentation and record review. UKDRS' compliance with the AB's requirements will be evaluated by reviewing our documentation versus the AB's checklists. The AB assessor will provide a written report of findings and UKDRS laboratory management will be given an exit briefing, including specific written identification of any deficiencies.

Hopefully, all significant deficiencies will be pointed out, so that during the initial assessment, only minor deficiencies, if any are found! A deficiency is any nonconformity to accreditation requirements. This may include a laboratory's inability to perform a test on the scope of accreditation. This could be due to equipment failure or the authorized personnel not being present the day of assessment. Also, the AB could determine the laboratory's management system does not conform to a clause or section of ISO 17025:2017, is not adequately documented, or is not completely implemented. Finally, a deficiency may be due to nonconformance of any additional requirements of the AB or programs necessary to meet customer's needs.

Any deficiencies preventing the laboratory from attaining accreditation are discussed with laboratory management and the assessor. The assessor also provided a final written report of findings that identify deficiencies. The laboratory has 30 days to respond in writing after the date of the exit briefing detailing either its corrective action or why it does not believe that a deficiency exists. The corrective action response must include the laboratory's cause analysis and a copy of any objective evidence to indicate that the corrective actions have been implemented/completed. It is possible that the assessor's review of the corrective action response may be needed to determine if the response is satisfactory.

It is entirely possible that the laboratory will disagree with the findings that one or more items are deficiencies. In this scenario, the laboratory is requested to explain in its response why it disagrees with the assessor. The deficiency and laboratory's

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explanation will be classified as a contested deficiency and provided to the Accreditation Council for a decision on validity. A new laboratory must resolve all deficiencies within four months of the exit briefing.

Of course, once initial accreditation to the ISO standard has been obtained, a surveillance assessment is required. This is initiated about six months prior to the midpoint of our accreditation cycle, which is typically about 18 months after accreditation has been achieved. This is usually a one-day assessment to confirm our management system is still in place. All deficiencies must be resolved within 60 days of the exit briefing.

The whole accreditation is a two-year cycle: year one is the initial, in-depth assessment by the AB; year two is considered a surveillance assessment. Then, year 3 begins the cycle over again! So around 3 months prior to the expiration of our accreditation, the annual review process begins again. The number of methods may be added to the scope of accreditation.

Someone once said, "the devil's in the details", and this is certainly true to become ISO 17025:2017 accredited.

Dr. Sharon F. Webb,
Director of Quality

Inspection Review for 2019

The Division of Regulatory has eight field inspectors that perform sampling and inspections at all agricultural facilities within the state of Kentucky. The four program areas the inspectors are responsible for are feed, fertilizer, seed, and agricultural lime. These include any manufacturing facilities, all retail ag stores including lawn and garden centers in addition to all pet food retail stores, and lime quarries.

The goal of the inspection program is to ensure safe products for the consumer and/or animals. The inspectors sample feed for livestock and pets to make sure the manufacturing process is correctly meeting the nutritional guarantees. We also test medicated feeds for the correct level of the drug being used for treating animals. Sampling fertilizer is to make sure the fertilizer product is meeting the analysis guarantees on the label. Seed samples are tested for germination, purity and weed seed present. Lime samples are analyzed for the Relative Neutralizing Value of a ton of lime needed to correct the pH of the soil. In addition to sampling products the inspectors are also looking at all labels for feed, fertilizer and seed products sold in Kentucky to make sure they are labeled correctly.

Inspections are also conducted at feed manufacturing facilities to make sure the cGMP's (current Good Manufacturing Practices) and being implemented for the type of facility and the feed being produced. During the inspections the inspectors are checking production processes and equipment along with other facility related issues such as cleanliness or any issue that could affect feed safety.

For all fertilizer facilities that blend, the inspection and sampling of custom mixes is to ensure the fertilizer blender is properly working and the mixing process is adequate for the fertilizer to meet the custom mix guarantees.

This past year the inspectors collected 3,149 feed samples. This would include livestock feed, bulk ingredients, minerals, bulk custom mixed livestock feed, pet food, pet treats, and specialty pet food products. There were 2,647 fertilizer samples collected this year and those were bulk bin materials, custom mixes, bagged fertilizer, liquid fertilizer and specialty products. There were 1,711 seed samples collected this year and those consist of ag crop seed, grasses, clovers, vegetables, and lawn and garden products. The lime program goal is to test the lime quarries twice each year, once in the spring and once in the fall. The total lime samples for the year was 137.

Microbiological research shows that handling pet foods and pet treats contaminated with some strains of *Salmonella*, *Listeria*, and/or *E. coli* can lead to infections in animals and people. To continue to protect Kentucky consumers, in 2019 UKDRS expanded its testing capabilities by adding *Listeria* and *Salmonella* testing. We tested 102 samples for these contaminants. Of that 102, 73 were tested for both *Salmonella* and *Listeria*. A total of 89 samples were tested for *Listeria* and 86 samples were tested for *Salmonella.* Our contaminant testing program is run in a unique way. Only unopened packages of animal feed, pet food, and treats are pulled specifically for contaminant testing. These products are submitted to the lab through our inspection program throughout the state and through targeted online purchasing. When contaminants are not detected, those samples are then allowed to be tested for nutritive analytes.

The University of Kentucky Division of Regulatory Services continues to maintain its role in consumer protection, provide services to agribusinesses, and provide a level playing field for those in agribusiness.

Jim True
Inspector Coordinator

Jonathan Collett wins 2019 Poundstone Award.

Jonathan Collett was awarded the Poundstone Award at our 2019 Christmas luncheon. Jon has been working full time at Regulatory Services since July of 2013 but had worked here previously as a student. He started out in the Feed and Fertilizer laboratory analyzing Nitrogen. When the opportunity presented itself, he took a job as a purity analyst in the seed lab but also received training as a Feed Microscopist and still serves in that capacity as well. He has served on several committees within the Division including a term as President of the Staff Senate.

Jon has a B.S. in Forestry from UK and recently finished a Master's Degree. He lives in Richmond.

As one of his nominators put it: "Jon is very deserving of the Poundstone Award. He exhibits an air of what a positive, dedicated and enjoyable employee can be and is appreciated by many."

Congratulations to Jon and thank you for all you do for Regulatory Services.

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
Rajna Tosheva-Tounova	2018	Feed/Fertilizer Lab
Marilyn Smith	2017	Seed Department
Gary Coleman	2016	Feed/Fertilizer Lab
Stephany Chandler	2015	Reception/Data Entry
June Crawford	2014	Fertilizer Department

Upcoming Meetings

ABAK Pesticide Management Workshop
Tuesday, February 11, 2020
9:00 am-4:00 pm
Holiday Inn-Louisville East
https://kyagbusiness.org/pesticide-workshop

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

Kentucky Dairy Partners Annual Meeting and Young Dairy Producers Meeting
February 25-26, 2020
Sloan Convention Center
Bowling Green, KY
http://www.kydairy.org/ydpkdp-conference.html

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