Regulatory Services News

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Director's Digest

TRAINING OFFERED

Hopefully those of you in the feed business are aware that the Food Safety Modernization Act (FSMA) Current Good Manufacturing Practice (CGMP) regulations became effective September 9, 2016 for companies with more than 500 employees. Small businesses with less than 500 full-time equivalent employees are required to be compliant with CGMP requirements starting September 18, 2017 and very small businesses (less than $2.5 million in annual sales) must be compliant by September 17, 2018. As part of meeting this requirement your business must have a Preventive Controls Qualified Individual (PCQI). FSMA rules define a PCQI as "a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system". The PCQI will be responsible for preparing, implementing, and managing the Food Safety Plan for the business. The PCQI doesn't necessarily have to be an internal employee but for most businesses that will be the most logical choice.

An individual may become a PCQI by successfully completing the Food Safety Preventive Controls Alliance (FSPCA) training course. These courses have and continue to be offered around the country and are required of many state inspectors as well as industry personnel. We are hosting a training here in Kentucky on October 10-12, 2017 at the Holiday Inn and Convention Center in Bowling Green, Kentucky. Class size will be limited to 60 people in order to allow adequate one to one instruction. We have 12 from our Division participating so we are opening up the training for 48 other individuals that may come from industry or other regulatory agencies. The cost of the course is $175.00/person which covers the cost of the manual, certificate, plus two lunches and breaks during the meeting. We have a block of rooms at the Holiday Inn that are available for $99.00/night. If you have an individual(s) in your company that needs this training, I would encourage them to sign up soon. Deadline for applying is September 9, 2017 or until the course fills up. A brochure and registration form for this meeting is attached with this newsletter or may be accessed on our website at the following link:

http://www.rs.uky.edu/FSPCA/

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What's Inside

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Regulatory Services

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We hope this meeting will be beneficial for your business and please let myself or Dr. Harrison know if you have any questions. Our contact information is on the second page of this newsletter.

MORE ON BEING AN AGVOCATE

I recently attended a national meeting where a panel discussion centered on defining sustainability for agriculture and what that term meant to different groups such as industry, farmers, consumers, and non-government organizations (in this case the World Wildlife Fund). The discussion was lively but civil and all agreed we have a challenging task of meeting future food demands and assuring consumers we are doing so in a responsible manner.

Several speakers emphasized what I discussed in the last issue about being responsible for promoting agriculture. One speaker pointed out an interesting fact about social media. He indicated studies show that for those on social media (Facebook, Twitter, Instagram, etc.) you will have an average of 59 contacts with no connection to agriculture. He indicated we should take this opportunity to post facts about agriculture in an effort to educate those contacts. I got to thinking about my contacts on Facebook and while most are related to agriculture, I realized several contacts from church, family, and other social contacts were not. I have started posting Farm Facts about twice per week and have been pleasantly surprised at the feedback I have received from my non-agricultural friends and several of my ag friends have reposted my Farm Facts which expands the audience even further.

If you decide to do this, please make sure your facts are accurate so it doesn't come back to haunt you. I stay with facts provided by either government surveys or groups such as the Beef Board, Egg Board, Pork Board or extension publications. I try to mix in a combination of interesting facts plus those that point out how important agriculture is to the world. Below is a short list of some you might consider and I am happy to provide more if you are interested. Give this a try at least once or twice and see what kind of feedback you receive. If you are not into social media, then try putting some of these at the end of an email or letter being sent to people with no agriculture background.

- During the War of 1812, a New York pork packer named Uncle Sam Wilson shipped a boatload of several hundred barrels of pork to U.S. troops. Each barrel was stamped "U.S." on the docks, and it was quickly said that the "U.S." stood for "Uncle Sam," whose large shipment seemed to be enough to feed the entire army. This is how "Uncle Sam" came to represent the U.S. Government.
- To make one pound of honey, the bees in the colony must visit 2 million flowers, fly over 55,000 miles and will be the lifetime work of approximately 300 bees.
- Farmers and ranchers receive only 16 cents out of every dollar spent on food at home and away from home. The rest goes for costs beyond the farm gate: wages and materials for production, processing, marketing, transportation and distribution. In 1980, farmers and ranchers received 31 cents. Farming is often said to be the only business where producers buy all inputs at retail prices and sell their product at wholesale prices.
- Because horse's eyes are on the side of their head they are capable of seeing nearly 360 degrees at one time.
- Over 98% of the beef animal is used when it is processed. About 45% of the animal is used for meat and the rest is used for other byproducts including leather, china, glue, film, soap, pharmaceuticals, insulin, gelatins. The meat from cattle is called beef. The average American eats about 65 pounds of beef each year.
- The hide from one cow can make 144 baseballs, 20 footballs or 12 basketballs.
- Cattle consume less than 2/10ths of 1% of all water used in the United States.
- A pig's squeal can range from 110-115 decibels. Compare that to the Concorde jet, which is usually under 112 decibels.

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Directors Digest, continued

- Insulin and about 40 other medicines are made from pigs.
- Americans spend 10% of their income on food, which is the lowest of any country.

Please promote agriculture every chance you get.

"You are not only responsible for what you say, but also for what you do not say."- Martin Luther

Dr. Darrell Johnson,
Executive Director

Cooperative Agreement between USDA and the Division of Regulatory Services and Labeling Requirements of the Federal Seed Act

The Division of Regulatory Services and USDA have had a Cooperative Agreement for as long as I can remember. All of our inspectors are authorized by USDA to draw samples of, secure information and inspect records pertaining to, and otherwise inspect seeds and screenings subject to the Federal Seed Act and regulations within Kentucky. The Cooperative Agreement indicates that our office will (1) Draw and inspect samples of seed within the State, subject to the Federal Seed Act, (2) Submit to the Federal Agency samples of seed shipments that are believed to be subject to and in violation of the Act which will include available records and other information indicating that the Act has been or is being violated.

Seeds which cross state lines have specific labeling requirements which are outlined below:

Contents of the label. The label shall contain the required information in any form that is clearly legible and complies with the regulations in this part. The information may be on a tag attached securely to the container, or may be printed in a conspicuous manner on a side or the top of the container. The label may contain information in addition to that required by the act, provided such information is not misleading.

Kind. The name of each kind of seed present in excess of 5 percent shall be shown on the label and need not be accompanied by the word "kind." When two or more kinds of seed are named on the label, the name of each kind shall be accompanied by the percentage of each. When only one kind of seed is present in excess of 5 percent and no variety name or type designation is shown, the percentage of that kind may be shown as "pure seed" and such percentage shall apply only to seed of the kind named.

Variety. (a) The following kinds of agricultural seeds are generally labeled as to variety and shall be labeled to show the variety name or the words "Variety Not Stated."
Alfalfa; Bahiagrass; Barley; Bean, field; Beet, field; Brome, smooth; Broomcorn; Clover, crimson; Clover, red; Clover, white; Corn, field; Corn, pop; Cotton; Cowpea; Crambe; Fescue, tall; Flax; Lespedeza, striate; Millet, foxtail; Millet, pearl; Oat; Pea, field; Peanut; Rice; Rye; Safflower; Sorghum; Sorghum-sudangrass, Soybean; Sudangrass; Sunflower; Tobacco; Trefoil, birdsfoot; Triticale; Wheat, common; Wheat, durum.

(b) If the name of the variety is given, the name may be associated with the name of the kind with or without the words "kind and variety." The percentage in such case, which may be shown as "pure seed," shall apply only to seed of the variety named, except for the labeling of hybrids as provided in §201.11a. If separate percentages for the kind and the variety or hybrid are shown, the name of the kind and the name of the variety or the term "hybrid" shall be clearly associated with the respective percentages. When two or more varieties are present in excess of 5 percent and are named on the label, the name of each variety shall be accompanied by the percentage of each.

Type. (a) When type is designated, such designation may be associated with the name of the kind but shall in all cases be clearly associated with the word "type." The percentage, which may be shown as "pure seed", shall apply only to the type designated. If separate percentages for the kind and the type are shown, such percentages shall be clearly associated with the name of the kind and the name of the type.

(b) If the type designation does not include a variety name, it shall include a name descriptive of a group of varieties of similar character and the pure seed shall be at least 90 percent of one or more varieties all of which conform to the type

Cooperative agreement, continued

designation.

(c) If the name of a variety is used as a part of the type designation, the seed shall be of that variety and may contain: (1) An admixture of seed of other indistinguishable varieties of the same kind and of similar character; or, (2) an admixture of indistinguishable seeds having genetic characteristics dissimilar to the variety named by reason of cross-fertilization with other varieties. In either case, at least 90 percent of the pure seed shall be of the variety named or upon growth shall produce plants having characteristics similar to the variety named.

Hybrid. If any one kind or kind and variety of seed present in excess of 5 percent is "hybrid" seed, it shall be designated "hybrid" on the label. The percentage that is hybrid shall be at least 95 percent of the percentage of pure seed shown unless the percentage of pure seed which is hybrid seed is shown separately. If two or more kinds or varieties are present in excess of 5 percent and are named on the label, each that is hybrid shall be designated as hybrid on the label. Any one kind or kind and variety that has pure seed which is less than 95 percent but more than 75 percent hybrid seed as a result of incompletely controlled pollination in a cross shall be labeled to show (a) the percentage of pure seed that is hybrid seed or (b) a statement such as "Contains from 75 percent to 95 percent hybrid seed." No one kind or variety of seed shall be labeled as hybrid if the pure seed contains less than 75 percent hybrid seed.

Name of kind and variety. The representation of kind or kind and variety shall be confined to the name of the kind or kind and variety determined in accordance with §201.34. The name shall not have affixed thereto words or terms that create a misleading impression as to the history or characteristics of the kind or variety.

Lawn and turf seed mixtures. Seed mixtures intended for lawn and turf purposes shall be designated as a mixture on the label and each seed component shall be listed on the label in the order of predominance.

Lot number or other identification. The lot number or other identification shall be shown on the label and shall be the same as that used in the records pertaining to the same lot of seed.

Origin. (a) Alfalfa, red clover, white clover, and field corn (except hybrid seed corn) shall be labeled to show: (1) The origin, if known; or (2) if the origin is not known, the statement "origin unknown."

(b) Whenever such seed originates in more than one State, the name of each State and the percentage of seed originating in each State shall be given in the order of its predominance. Whenever such seed originates in a portion of a State, it shall be permissible to label such seed as originating in such portion of a State.

(c) Reasonable precautions to insure that the origin of seed is known shall include the maintaining of a record as described in §201.5. The examination of the seed and any pertinent facts may be taken into consideration in determining whether reasonable precautions have been taken to insure the origin to be that which is represented.

Weed seeds. The percentage of weed seeds shall include seeds of plants considered weeds in the State into which the seed is offered for transportation or transported and shall include noxious weed seeds.

Noxious-weed seeds. (a) Except for those kinds of noxious-weed seeds shown in paragraph (b) of this section, the names of the kinds of noxious-weed seeds and the rate of occurrence of each shall be expressed in the label in accordance with, and the rate of occurrence shall not exceed the rate permitted by, the law and regulations of the state into which the seed is offered for transportation or is transported. If in the course of such transportation, or thereafter, the seed is diverted to another State of destination, the person or persons responsible for such diversion shall cause the seed to be relabeled with respect to the noxious-weed seed content, if necessary to conform to the laws and regulations of the State into which the seed is diverted.

(b) Seeds or bulblets of the following plants shall be considered noxious-weed seeds in agricultural and vegetable seeds transported or delivered for transportation in interstate commerce (including Puerto Rico, Guam, and the District of Columbia). Agricultural or vegetable seed containing seeds or bulblets of these kinds shall not be transported or delivered for transportation in interstate commerce. Noxious-weed seeds include the species on which

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no tolerance will be applied:

A list of noxious-weed seeds can be found at the following link:

https://www.ecfr.gov/cgi-bin/text-idx?SID=91e5813f780af02c6ae47dbb282c756b&mc=true&node=sg7.3.201_17a.sg4&rgn=div7

Noxious-weed seeds in the District of Columbia. Noxious-weed seeds in the District of Columbia are: Quackgrass (*Elytrigia repens*), Canada thistle (*Cirsium arvense*), field bindweed (*Convolvulus arvensis*), bermudagrass (*Cynodon dactylon*), giant bermudagrass (*Cynodon dactylon* var. *aridus*), annual bluegrass (*Poa annua*), and wild garlic or wild onion (*Allium canadense* or *Allium vineale*). The name and number per pound of each kind of such noxious-weed seeds present shall be stated on the label.

Other agricultural seeds (crop seeds). Agricultural seeds other than those included in the percentage or percentages of kind, variety, or type may be expressed as "crop seeds" or "other crop seeds," but the percentage shall include collectively all kinds, varieties, or types not named upon the label.

Inert matter. The label shall show the percentage by weight of inert matter.

Germination. The label shall show the percentage of germination for each kind or kind and variety or kind and type of kind and hybrid of agricultural seed present in excess of 5 percent or shown in the labeling to be present in a proportion of 5 percent or less.

Hard seed. The label shall show the percentage of hard seed, if any is present, for any seed required to be labeled as to the percentage of germination, and the percentage of hard seed shall not be included as part of the germination percentage.

Date of test. (a) The label shall show the month and year in which the germination test was completed. No more than 5 calendar months shall have elapsed between the last day of the month in which the germination test was completed and the date of transportation or delivery for transportation in interstate commerce, except for seed in hermetically sealed containers as provided in §201.36c in which case no more than 24 calendar months shall have elapsed between the last day of the month in which the germination test was completed prior to packaging and the date of transportation or delivery for transportation in interstate commerce.

(b) In the case of a seed mixture, it is only necessary to state the calendar month and year of such test for the kind or variety or type of agricultural seed contained in such mixture which has the oldest calendar month and year test date among the test conducted on all the kinds or varieties or types of agricultural seed contained in such mixture.

(c) The following kinds shall be tested within the indicated time before interstate shipment:

Agricultural seeds and mixtures thereof	Months from test date to shipment
Bentgrass, Colonial	15
Bentgrass, Creeping	15
Bluegrass, Kentucky	15
Fescue, Chewings	15
Fescue, Hard	15
Fescue, Red	15
Fescue, Tall	15
Ryegrass, Annual	15
Ryegrass, Perennial	15

Name of shipper or consignee. The full name and address of either the shipper or consignee shall appear upon the label. If the name and address of the shipper are not shown upon the label, a code designation identifying the shipper shall be shown.

Code designation. The code designation used in lieu of the full name and address of the person who transports or delivers seed for transportation in interstate commerce shall be approved by the Administrator of the Agricultural Marketing Service or such other person as may be designated by him for the purpose. When used, the code designation shall appear on the label in a clear and legible manner.

Inoculated seed. Seed claimed to be inoculated shall be labeled to show the month and year beyond which the inoculant on the seed is no longer claimed to be effective by a statement such as, "Inoculant not claimed to be effective after____ (Month and year)."

Steve McMurry,
Director of Fertilizer and Seed Programs

Animal Feed Ingredient Definitions

The sampling of commercial feed and the reporting of sample analyses is one of the more visible aspects of our feed program. Under the Kentucky feed laws and regulations our division is responsible for ensuring that sample guarantees are met and that the consumer is getting the product that they paid for. But our division is also responsible for ensuring that only approved ingredients are used in commercial feeds distributed in the state.

Our regulations mandate that all ingredients that are used in the formulation of a commercial feed be approved by the Association of American Feed Control Officials (AAFCO). *The names and definitions for commercial feeds shall be the 'Official Definition of Feed Ingredients' adopted by the Association of American Feed Control Officials and published in its Official Publication, except as exempted by an administrative regulation promulgated by the director. (12 KAR 2:006(Section 1))*

Ingredients with definitions published in the AAFCO Official Publication are "known quantities". We know where the ingredient came from, we know how it was produced, there is a history of how the ingredient has been used, and they are considered safe for the intended purpose. Conversely, we would not have all this information with an unapproved ingredient.

New ingredients do have a path for approved use in animal feeds. For example, industrial hemp production in Kentucky and other states may produce byproducts suitable for animal feed. At this time, these byproducts do not have approved ingredient definitions and Kentucky is not accepting hemp products as single ingredients or as a component of any animal feed including pet foods. However, we do expect that at some point in the near future, ingredient definitions will be submitted to AAFCO and products like hemp seed meal and hemp oil will be evaluated as potential animal feeds.

AAFCO Ingredient Definition Approval Process

The complete AAFCO process for new ingredient definitions can be found at (http://www.aafco.org/Portals/0/SiteContent/Regulatory/Committees/Ingredient-Definitions/definition_request_guidelines_020112.pdf). Regardless of who requests a new ingredient definition, these are non-proprietary and do not favor one ingredient producer over another. A feed ingredient cannot be a combination of other ingredients. The intended use should not be to mitigate, treat or diagnose a disease, but rather to provide nutrition, color, taste, or aroma for the animal. It is the manufacturer's responsibility to produce a safe ingredient for its intended purpose. Here's the shortened version of how this process works.

The process starts with a requester (industry, public, regulatory official, etc.) contacting the appropriate AAFCO investigator. The investigator will review the submission packet for completeness. In a nutshell, the investigator will need to see the proposed definition, manufacturing information, proposed use or purpose of the ingredient, data to support use, and a summary of safety assessment. The investigator will send the submission packet to FDA's Center for Veterinary Medicine (CVM). When FDA has finished their review, the investigator will prepare and forward an "Investigators Report" form to the chair of the AAFCO's Ingredient Definitions Committee. The committee will consider the request, forward a recommendation to AAFCO's Board of Directors, and the board will forward their recommendation to the full AAFCO voting membership. This entire process can take a couple of years but if the ingredient is approved, the majority of states will accept the ingredient.

Dr. G. Alan Harrison,
Director of Feed and Milk Programs

Pet Owners In the Know – What Does "Natural" Mean?

It seems that these days it is practically impossible to walk down the pet food aisle without seeing pet food products claiming to be "Natural", "All natural" and "Natural with added vitamins and minerals." Sounds good, but what does this actually mean to the informed consumer?

The Association of American Feed Control Officials (AAFCO) has developed guidelines for use of the term "Natural" on product labels. The use of the term "natural" is only acceptable in reference to the product as a whole when all of the ingredients and components of ingredients meet the definition.

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However, AAFCO recommends that exceptions be made in the cases when chemically synthesized vitamins, minerals, or other trace nutrients are present as ingredients in the product, so long as the product is not a dietary supplement. In addition a disclaimer must be included to inform the consumer that the vitamins, minerals or other trace minerals are not natural. This is because many readily available sources of essential dietary vitamins and minerals, required to keep your pets healthy, are almost exclusively chemically synthesized or subject to processes that do not fall within the "natural" definition.

The Association of American Feed Control Officials (AAFCO) defines "Natural" as: A feed or ingredient derived solely from plant, animal or mined sources, either in its unprocessed state or having been subject to physical processing, heat processing, rendering, purification, extraction, hydrolysis, enzymolysis or fermentation, but not having been produced by or subject to a chemically synthetic process and not containing any additives or processing aids that are chemically synthetic except in amounts as might occur unavoidably in good manufacturing practices.

This means that any product claiming to be "Natural with added vitamins and minerals" must not contain, for example, artificial colors, artificial flavors or chemically synthesized preservatives, but can contain chemically synthesized vitamins and minerals.

Products claiming to be "All natural" or "Natural" with no disclaimer, may not contain any non-natural or chemically synthesized ingredients.

Kristen Green,
Registration Specialist

Off-Target Movement of Dicamba

Over the past few months there has been considerable discussion over the use of Dicamba in Soybean production. By no means am I an expert in this area but I have been reading a few articles on the subject and I assume many articles have yet to be written as the cases related to off-target movement of Dicamba have yet to be resolved. Below are some links to articles I felt are interesting on the subject.

Ag Industry, Do we have a problem yet?
Posted July 25, 2017 by Kevin Bradley
https://ipm.missouri.edu/IPCM/2017/7/Ag_Industry_Do_we_have_a_problem_yet/

The Dicamba Dilemma in Illinois: Facts and Speculations
Posted on July 18, 2017 by Aaron Hager
http://bulletin.ipm.illinois.edu/?p=3942

"I can't keep dicamba in the field"
Posted July 18, 2017 by Larry Steckel, Extension Weed Specialist
http://news.utcrops.com/2017/07/cant-keep-dicamba-field/

Steve McMurry,
Director of Fertilizer and Seed Programs

Labeling and Registering VFD Medicated Feeds

On January 1st, 2017, the updated Veterinary Feed Directive (VFD) Rule came into effect. The Division of Regulatory Services has already written a great deal on VFDs, with quite a bit of useful information available on our website at: http://www.rs.uky.edu/regulatory/feed/VetDirective.php. This article will focus on the proper labeling and registration of VFD medicated feeds in Kentucky.

VFD medicated feed labels are now all required to include the following statement - "CAUTION: Federal law restricts medicated feed containing this Veterinary Feed Directive (VFD) drug to use by or on the order of a licensed veterinarian." In addition, production claims for VFD drugs such as "for increased rate of weight gain" and "for improved feed efficiency" are no longer allowed. The website listed above contains links to the updated FDA Bluebird labels and to the Division's own 'Feed Labels' which provide updated VFD medicated label examples.

The Food and Drug Administration (FDA) has allowed the use of transition labeling for VFD products that were expected to be in the marketplace both before and after January 1st. Transition labels contained both the previously approved drug indications and levels as well as the newly required caution statement. The Division expects that most of this transition labeling should now have worked its way out of the marketplace. VFD medicated feeds currently in the marketplace should be compliant with

the VFD Rule and all new VFD products submitted for registration are reviewed for adherence to the VFD Rule.

Manufacturers, please note that any products that were previously accepted for registration by the Division under the old VFD Rule which are no longer in compliance with the updated VFD Rule are not considered to be currently registered by the Division. Firms that have revised their VFD labels to be compliant with the updated VFD Rule are encouraged to submit copies to the Division so that we have the correct version of your labeling on file.

Kristen Green,
Registration Speicalist

Document Control in ISO 17025

This quarter I will discuss the role and importance of document control as we move through the accreditation process requirements. ISO 17025 requires as part of a quality system that all documents which are part of the management system be controlled by procedures. The term "document" is interpreted with the broadest meaning as covering all information in all forms, including computer files, software and other electronic or digital information. This includes regulations, standards, policies, procedures, methods, instructions, manuals, diagrams, software, calibration tables, books, notices, memoranda, plans, and specifications. What ISO wants to accomplish with this requirement is to make sure that the most current method, policy, etc. is the one that all staff are using while performing their duties.

One of the reasons a document control system is required is to ensure that management is aware of and has approved all the documents in use by the staff to guide them in their work. Another reason is to ensure that all documents specifying procedures have been checked by someone with appropriate knowledge to ensure they are accurate, technically sound, and unambiguous. Also, the document control is supposed to track all records of the issuing of all copies of documents, so that if documents need to be reviewed, withdrawn, or amended, all the copies can be subjected to the same procedure. The document control system does not need to be unnecessarily elaborate, as long as it meets the laboratory's needs.

When establishing a document control system, those with the relevant knowledge should be the ones who review specific documents prior to the documents being issued. This isn't an issue of management hierarchy. For example, if the issue is whether a document is a correct and clear description of a bench procedure, the best person to review it might be a technician who routinely does the work. The document control system should also allow for the documents to be issued and amended quickly by the most qualified person. If the document issues and revisions do have cross department implications and need some discussion, the procedure for reaching the agreement should be streamlined and made efficient and not be excessively bureaucratic. The purpose of the document control system is to allow appropriate and accurate documents to be issued, amended, and withdrawn without being obstructive.

All documents issued to the personnel in the laboratory as part of the management system must be reviewed and approved for use by authorized personnel prior to issue. The documents have to be identified in a master list along with the current revision status. The document control system has to establish the distribution of documents and should prevent the use of invalid and/or obsolete documents. Allowance should be made in the quality manual for the issuing of uncontrolled copies of controlled documents but only outside the organization. Having this allowance in the quality manual addresses the need, should it arise, to provide customers or other organizations with copies of the controlled document. Any documents issued as "uncontrolled" should be clearly marked as such, by either a watermark or a stamp.

ISO also requires, or rather the assessors, who determine if the laboratory is meeting the standard, that any published documents including technical methods that are subject to revisions by the issuing body meet the ISO standard for document control. This means there must be a process in the document control system to address exchanging the older documents for the updated versions. Typically, this is handled by including in the system a person and a defined process to periodically check with the publisher of such documents/methods to determine if any changes have been made and what actions to take if there have been.

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ISO 17025 also requires control of any forms used for records or data generated by the laboratory. The data on the form changes with each batch of samples analyzed or calibration checked, so it is really the format of these forms that is being controlled. The master set of forms is what is controlled. Any copies made for use, whether electronically or a hard copy must be generated from the controlled master set and not from any copies or uncontrolled sets. Each set of master forms that are controlled within the document control system must be numbered, dated with issue date, version listed, and updated in the master list of documents controlled within the system. These forms are also subject to review according to the review process within the document control system.

Each staff member is also charged with certain requirements and/or authorities within the document control system. For example, analysts and/or techs may be responsible and are expected to report to either their supervisor, lab manager/director, or the quality director if their bench sheet steps don't match what the steps in the SOP. Supervisors in turn may be charged with making sure safety requirements in the SOP are current with the requirements of the laboratory. The lab manager or director could be responsible for the maintenance of all hard copy controlled documents assigned to a staff member. The quality unit is the issuing authority for all quality management system documents, maintains the master lists of controlled documents, implements and maintains the document control system, among other responsibilities.

As you can tell by this very brief description of the document control system, there are a lot of details that must be described, defined, reviewed, and agreed upon by the management team. The document control system ensures that documents describing operational and testing policies and procedures are current, complete and that obsolete documents are removed from use and replaced when new versions are issued. This applies to policies, procedures, forms, bench sheets, reference methods, regulations, standards, operation manuals, and forms. The main take away from every sub clause in the ISO 17025 standard is to make sure that "you do what you say and say what you do", with "say" actually meaning "write" and/or "document".

As you read these articles, I hope that your appreciation of the large task ahead of us continues to grow. We undertook this project to be beneficial for the consumers, producers, and manufacturers of Kentucky and to benefit us as an organization. I hope that you can see that this undertaking is further proof of our commitment to continually improve what we do and how we do it so that our Regulatory Programs keep producing unbiased, accurate, and timely results from our laboratories.

Dr. Sharon F. Webb,
Director, Quality Program

Upcoming Meetings

Association of American Plant Food Control Officials (AAPFCO)
2017 Annual Summer Meeting
August 6-9, 2017
Bellevue, WA 98004
http://www.aapfco.org/meetings.html

American Association of Feed Control Officials (AAFCO)
2017 Annual Meeting
August 10-12, 2017
Bellevue, Washington
http://www.aafco.org/Meetings

Industrial Hemp Research Field Day
University of Kentucky Spindletop Research Farm
August 11, 2017-8:00 am to 12:00 pm

FSPCA Preventive Controls for Animal Food training
October 10-12, 2017
Holiday Inn University Plaza
1021 Wilkinson Trace
Bowling Green, KY
http://www.rs.uky.edu/FSPCA/

Personnel News

Charlene Vest retired from Regulatory Services on July 4, 2017. Charlene started working for Regulatory Services on May 15, 1972 as a Data Entry Operator. To save you doing the math, she had worked for us for 45 years and 1 month at the time of her retirement. As you can imagine, the way we enter data has changed tremendously during that time. Charlene started out punching cards and ended up entering all data through the computer keyboard. She put up with many changes over the years but always adapted to the new systems. Attention to details is a key component of this position and Charlene was adamant that things be done right. We all hope she enjoys a well deserved retirement and are grateful for her many years of service.

Garland McKee will be retiring from Regulatory Services on August 1. Garland has been a key member of our Feed and Fertilizer lab for over 30 years. He has been responsible for analysis of phosphate, potash and sulfate in fertilizer. Garland also has a rare skill in that he was our primary feed microscopist. Garland has also helped out with various feed analyses during his career such as Vitamin A, fat and fiber.

Garland is looking forward to a more relaxed schedule in retirement plus time to catch up on yard work and devoting more time to photography.

If any of you have called our feed office during the last 39+ years you have probably talked to Kay Phillips. Kay will be retiring on August 3. She has worked for four different full time feed directors and 2 interim directors during her time here. It is hard to imagine what our feed division will look like without Kay as a stabilizing force.

Kay lives in Versailles and plans on spending 3 days per week babysitting her granddaughter after retirement. She also plans to spend more time on their family farm which is located near Princeton, Ky.

Congratulations to our retirees and thank you for a combined 114+ years of work for Regulatory Services.

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College of Agriculture, Food and Environment

Regulatory Services

About the Course

This course, developed by the Food Safety Preventive Controls Alliance (FSPCA), is the standardized curriculum recognized by the U. S. Food and Drug Administration. Successfully completing this course is one way to meet the requirements for a preventive controls qualified individual (PCQI), under the Food Safety Modernization Act (FSMA) rules. Participants who are present for the entire course and actively participate in the exercises will receive a FSPCA certificate of completion (included in course registration cost). This course will be open to both regulatory and industry participants.

The FSMA Current Good Manufacturing Practice (CGMP) regulations became effective 9/19/2016 for companies with more than 500 employees. Small businesses with less than 500 full-time equivalent employees are required to be compliant with CGMP regulations starting 9/18/2017 and very small businesses must be compliant by 9/17/2018

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FSPCA Preventive Controls for Animal Food

October 10-12, 2017

Holiday Inn University Plaza
1021 Wilkinson Trace
Bowling Green, KY 42103
(270) 745-0088

University of Kentucky
Regulatory Services
College of Agriculture, Food and Environment

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Schedule

Tuesday, October 10: 9:30 a.m.-5 p.m.

Introductions and Welcome

Chapter 1– Regulatory Overview and introduction to the Rule

Lunch

Chapter 2 - Current Good Manufacturing Practice

Chapter 3 –Animal Food Safety Hazards

Chapter 4 –Overview of the Food Safety Plan

Wednesday, October 11: 8 a.m.-5 p.m.

Chapter 5 –Hazard Analysis and Preventive Controls Determination

Chapter 6 –Required Preventive Control Management Components

Chapter 7 –Process Preventive Controls

Chapter 8 –Sanitation Preventive Controls

Thursday, October 12: 8 a.m.-Noon

Chapter 9 –Supply Chain Applied Controls

Chapter 10 –Recall Plan

Wrap up and Adjourn

This course will be team taught by Lead Instructors for the FSPCA Preventive Controls for Animal Food Course.

David Fairfield is the Senior Vice President of Feed services for the National Grain and Feed Association (NGFA). Fairfield joined the NGFA staff in July 2001 after spending 20 years managing operations for major U.S. commercial feed companies. Fairfield is the chair of the animal food-related activities within the Food Safety Preventive Controls Alliance and is graduate in feed science from Kansas State University.

Matt Frederking is the Vice President of Regulatory Affairs and Quality Assurance for Mid America Pet Food. Frederking is an International HACCP Alliance Lead Instructor and was instrumental in developing the HACCP training course taught at KSU. He continues to teach HACCP courses at KSU for all sectors of the feed industry.

FSPCA Preventive Controls for Animal Food

Registration Form

The registration for this event is $175.00. This fee will cover the course materials, FSPCA course certificate fee, lunch, and refreshments during the meeting. This fee is lower than many others you will find due to a grant from AFDO and FDA. Other meals and lodging are at the attendees expense. **Class size is limited to 60 participants and deadline for registration is September 9, 2017 (or until class is full).**

Rooms are available for $99.00/night (plus taxes) and can be reserved by calling (270) 745-0088 and asking for rooms in the FSPCA block. If you want to book online the link is shown below and the booking code is UK7

www.HIBowlingGreen.com

Name _____

Company _____

Address _____

City, State, Zip _____

Phone _____

Email*_____

*email should be unique to the individual receiving the certificate (not a company email)

Return completed registration and payment to:

UK Division of Regulatory Services

103 Regulatory Services Building

Lexington, KY 40546

Please make checks payable to: UK Reg Services-FSPCA

For questions contact Darrell Johnson or Al Harrison (darrell.johnson@uky.edu or alan.harrison@uky.edu)

(859) 257-2785