Regulatory Services News

Vol. 58, No.3 Feed - Fertilizer - Milk - Seed - Seed Testing - Soil Fall 2015

Director's Digest- Third Quarter 2015

As mentioned in an earlier article, the duties of Regulatory Services began in 1886 with an act to regulate the sale of fertilizers in the state. At the beginning of 1918 the regulatory functions of the College of Agriculture in addition to fertilizer sales involved enforcement of laws relating to the sale of commercial feeds, foods and drugs, agricultural seeds, and nursery stock. Enforcement of the Pure Foods Law had been one of the outstanding success stories of the division since the law was passed in 1898. However, change was in the air and in 1918 the General Assembly moved enforcement of the Pure Foods Law to the Department of Public Health. During this same legislative session, a law was passed dealing with the weighing and sampling of milk and cream, providing for examination and certification of the glassware used in testing milk and cream for butterfat with the Babcock test, and providing for the examination and licensing of testers, fixing penalties for violation of the provisions of the act. These duties were given to the Division of Regulatory Services.

It is important to note that our role in the milk industry concerns dairymen being paid properly for the milk they produce. We are not involved in inspection of dairy parlors which is done through the Department for Public Health in Frankfort. The roles of our program include:

- Ensuring that milk haulers are making accurate measurements and conversions for the volume of milk in producer tanks and are obtaining a representative sample to be submitted for payment purposes.
- Monitoring the handling of producer samples from the hauler to the laboratory and ensure samples used for payment purposes are handled properly and analyzed in a timely manner.
- Monitoring laboratories that analyze producer samples for payment purposes. Labs are routinely evaluated to ensure they are following proper lab procedures and are utilizing accurately calibrated equipment.
- Reviewing pay records from weight tickets, to lab records, and final pay stubs to ensure that processors are billed accurately.
- Providing analyses for university research projects and also for private producers such as our growing artisan cheese business in the state.
- Analyzing milk samples from cows participating in the North American International Livestock Exposition.

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- Reproducing Bulk Milk Tank Conversion Charts for producers when the ones they have become difficult to read.
- Cooperating with other agencies on educational projects to provide a variety of services to Kentucky dairy producers, processors and allied industries.

We take seriously our role in ensuring that dairy farmers are paid correctly for what they produce and in general support of the Kentucky Dairy Industry. We have a Milk Handlers Advisory Board that meets annually and this board is one of the main avenues for the milk program to remain aware of Kentucky's dairy industry needs and concerns. Advisory Board input assists Regulatory Services in our effort to provide better service to Kentucky's dairy industry. The members of this board may be seen on our website at www.rs.uky.edu.

Highlights of our milk program activities for 2014 are shown below:

- Reviewed applications and issued licenses to 2 transfer stations, 22 milk handlers, 16 laboratories, 75 technicians, and 306 sampler-weighers (milk-haulers, receivers and samplers).
- Collaborated with Kentucky Cabinet for Health Services Milk Safety Branch to train sampler-weighers and processor receiving personnel. Trained and examined 19 new sampler-weighers and 7 new technicians.
- Conducted 10 pay-record and 13 raw milk receiving audits.
- Conducted 28 milk laboratory inspections.
- Conducted 368 sampler-weigher inspections and analyzed milk samples from 2,393 dairy herds to evaluate sampler-weigher performance and ensure accurate producer payments.
- Administered a monthly milk lab quality control check sample program through the distribution of 2376 samples to the 16 licensed laboratories and 2 other labs to ensure accurate component-analysis procedures.
- Provided analyses for university research projects pertaining to dairy cattle management and feeding practices effects on milk composition (135 samples analyzed in 2014).
- Provided analyses for Kentucky small processor cheese makers (168 samples).
- Analyzed milk samples from 72 cows in conjunction with cattle judging at North American International Livestock Exposition in Louisville.

The Division of Regulatory Services has eight inspectors out in the state who focus on fertilizer, feed and seed. We have one inspector dedicated strictly to milk. In addition to working in Kentucky, he must travel to other states where Kentucky milk is processed. In addition to our inspectors we have an additional 46 employees in Lexington and three in Princeton who work in support of all our programs. We are proud of what we have done to protect consumers, producers and agribusinesses in the Commonwealth for over 100 years and look forward to serving for many more.

Darrell Johnson, Director

History is from "The College of Agriculture of the University of Kentucky" by J. Allan Smith

Regulatory Services News is published quarterly for the feed, fertilizer, milk and seed regulatory programs and the seed and soil service testing programs of the Division of Regulatory Services. It is provided free to persons interested in these programs. For subscriptions or address changes, contact our office at (859) 257-2785. You can also access and sign up for Regulatory Services News on the Internet at http://www.rs.uky.edu.

The Fertilizer Institute
Nourish, Replenish, Grow

AGRICULTURAL RETAILERS ASSOCIATION

MEMORANDUM

TO: American Association of Plant Food Control Officials

FROM: Wade Foster, Manager, Regulatory and Scientific Affairs, The Fertilizer Institute
Kyle Liske, Public Policy Counsel, Agricultural Retailers Association

SUBJECT: Sulfur Dust Explosions in Fertilizer Retail Facilities

DATE: September 10, 2015

The Fertilizer Institute (TFI) and Agricultural Retailers Association (ARA) have become aware of sulfur dust exploding while being blended or handled at fertilizer retail facilities. Sulfur dust is highly combustible, and has a lower flash point than many other combustible dusts. This memo is to advise fertilizer retailers of the dangers of sulfur dust, and the potential for sulfur dust explosions.

Sulfur is an important plant nutrient, since the passage of the Clean Air Act, the amount of atmospheric deposition of sulfur has dropped across the United States. To compensate for the reduced atmospheric deposition farmers, and their agricultural retailers, are increasingly adding sulfur containing fertilizers to their crops.

The National Fire Protection Association Standard 655 (NFPA 655), *Standard for Prevention of Sulfur Fires and Explosions* (2012) addresses prevention of sulfur fires and explosions. As noted in the standard sulfur dust has a low ignition point of 190ºC and the dust clouds are readily ignited by weak frictional sparks. Dusts containing 25% or more of elemental sulfur may be almost explosive as pure sulfur. Sulfur has excellent electrical insulation properties and can pick up static electricity, which, when discharged can cause a spark that will ignite the dust cloud. Due to the potential dangers from handling sulfur it is advisable to review your safety and housekeeping procedures to ensure that equipment and facilities are maintained to minimize the risk of sulfur dust explosions.

The NFPA 655 Standard is available for free online. Attached is a fact sheet on sulfur prepared by the International Plant Nutrition Institute, and a fact sheet on combustible dust prepared by the Occupational Safety and Health Administration.

If you have any questions, please do not hesitate to contact either Wade Foster with The Fertilizer Institute via email at wfoster@tfi.org, or Kyle Liske with the Agricultural Retailers Association via email at kyle@aradc.com.

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IPNI Nutrient Source SPECIFICS

No. 13

Sulfur

Sulfur (S) is widely distributed throughout the world in many forms. In some soils, there is insufficient S to meet crop needs. There are many excellent S-containing fertilizer products that can be used to address deficiencies where they occur.

Production

Sulfur is a relatively abundant element in the earth's crust. It has been extracted as pure elemental S from volcanic deposits and salt domes. It is now more commonly obtained as a co-product from processing fossil fuels. Coal, crude oil, and natural gas typically contain between 0.1% and 4% S which is removed during refining or scrubbing of combustion gases. A variety of common earth minerals are used as S sources for agriculture.

Elemental S has a fairly low melting temperature (115 °C; 240 °F), so it is often transported and handled in a hot liquid state until it is transformed into final products. The majority of global S production is converted to sulfuric acid (H_2SO_4) for further processing. A major use of sulfuric acid is in production of phosphate fertilizers.

Common Sulfur Sources

Non-Soluble	Elemental S
Semi-Soluble	Gypsum (15 to 17% S)
Soluble	Ammonium sulfate (24% S); Epsom salt (13%); Kieserite (23% S); Langbeinite (22% S); Potassium sulfate (18% S); Thiosulfate (10 to 26% S)

Sulfur pastilles, containing small amounts of clay to enhance dispersion and oxidation

Elemental sulfur

Agricultural Use

Elemental S is not water soluble and must be oxidized by soil bacteria (such as *Thiobacillus*) to sulfate (SO_4^{2-}) before it can be taken up by plant roots. The general reaction in soil is: $2S + 3O_2 + 2H_2O \rightarrow 2H_2SO_4$. The speed of this microbial process is governed by environmental factors such as soil temperature and moisture, as well as the physical properties of the S.

Plants almost exclusively use sulfate as their primary source of nutrition, where it is converted to many essential constituents, such as proteins and enzymes. Various approaches have been used to enhance the conversion of elemental S to plant-available sulfate. The speed of elemental S oxidation is directly related to the particle size, where smaller particles have a greater surface area for the soil bacteria to act on. Therefore, large particles of S may require months or years of biological action before oxidizing significant amounts of sulfate. Fine, dust-sized particles are oxidized quickly, but are not easy to apply.

One approach to enhance the rate of S oxidation is to add a small amount of clay to the molten S prior to cooling and forming small pellets ("pastilles"). When added to soil, the clay swells with water and the pastille disintegrates into fine particles that are rapidly oxidized.

Very thin layers of elemental S can be incorporated during fertilizer granule manufacturing. This S is quick to oxidize and become available for plant uptake. This reaction can have a positive impact on the plant availability of some micronutrients, such as zinc (Zn) and iron (Fe), that become more soluble as the pH declines. Finely ground elemental S is sometimes added to fertilizer suspensions. Elemental S is widely used as a fungicide for crop protection, where toxic hydrogen sulfide is evolved from the interaction of elemental S and the living fungal tissue.

Elemental S and sulfuric acid are commonly used in the reclamation of soils that contain excessive sodium and in the treatment of some irrigation water.

Management Practices

Sulfur is available in many forms to meet specific cropping requirements. Elemental S is generally applied well in advance of crop demand, since a lag period of bacterial oxidation and conversion to sulfate is involved. Since sulfate is an anion, it may be subject to leaching loss, similar to nitrate. However, there are no adverse environmental impacts associated with typical concentrations of sulfate in water.

Non Agricultural Uses

Sulfur is widely used in many consumer products and industrial applications. It is commonly converted to sulfate prior to use in textiles, rubber, detergents, and paper, as examples.

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Nutrient Source Specifics is a series of brief, condensed fact sheets highlighting common fertilizers and nutrient sources in modern agriculture. These topics are written by scientific staff of the International Plant Nutrition Institute (IPNI) for educational use. Mention of a fertilizer source or product name does not imply endorsement or recommendation. This series is available as PDF files at this URL: >www.ipni.net/specifics<

Ref #13- 10073

OSHA® FactSheet

Hazard Alert: Combustible Dust Explosions

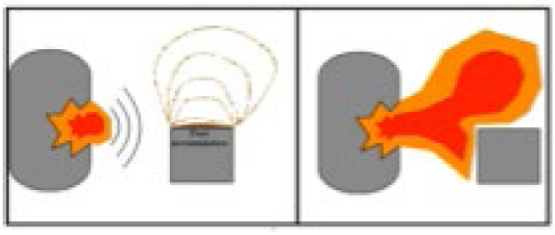
Combustible dusts are fine particles that present an explosion hazard when suspended in air in certain conditions. A dust explosion can be catastrophic and cause employee deaths, injuries, and destruction of entire buildings. In many combustible dust incidents, employers and employees were unaware that a hazard even existed. It is important to determine if your company has this hazard, and if you do, you must take action now to prevent tragic consequences.

How Dust Explosions Occur

In addition to the familiar fire triangle of oxygen, heat, and fuel (the dust), dispersion of dust particles in sufficient quantity and concentration can cause rapid combustion known as a deflagration. If the event is confined by an enclosure such as a building, room, vessel, or process equipment, the resulting pressure rise may cause an explosion. These five factors (oxygen, heat, fuel, dispersion, and confinement) are known as the "Dust Explosion Pentagon". If one element of the pentagon is missing, an explosion cannot occur.

Catastrophic Secondary Explosions

An initial (primary) explosion in processing equipment or in an area where fugitive dust has accumulated may dislodge more accumulated dust into the air, or damage a containment system (such as a duct, vessel, or collector). As a result, if ignited, the additional dust dispersed into the air may cause one or more secondary explosions. These can be far more destructive than a primary explosion due to the increased quantity and concentration of dispersed combustible dust. Many deaths in past incidents, as well as other damage, have been caused by secondary explosions.



A pharmaceutical plant after a dust explosion.

Industries at Risk

Combustible dust explosion hazards exist in a variety of industries, including: agriculture, chemicals, food (e.g., candy, sugar, spice, starch, flour, feed), grain, fertilizer, tobacco, plastics, wood, forest, paper, pulp, rubber, furniture, textiles, pesticides, pharmaceuticals, tire and rubber manufacturing, dyes, coal, metal processing (e.g., aluminum, chromium, iron, magnesium, and zinc), recycling operations, fossil fuel power generation (coal), and 3D welding (a form of 3D printing).

Prevention of Dust Explosions

To identify factors that may contribute to a explosion, OSHA recommends a thorough hazard assessment of:

- All materials handled;
- All operations conducted, including by-products;
- All spaces (including hidden ones); and
- All potential ignition sources.

Dust Control Recommendations

- Implement a hazardous dust inspection, testing, housekeeping, and control program;
- Use proper dust collection systems and filters;
- Minimize the escape of dust from process equipment or ventilation systems;
- Use surfaces that minimize dust accumulation and facilitate cleaning;
- Provide access to all hidden areas to permit inspection;
- Inspect for dust residues in open and hidden areas at regular intervals;
- If ignition sources are present, use cleaning methods that do not generate dust clouds;
- Use only vacuum cleaners approved for dust collection; and
- Locate relief valves away from dust deposits.

Ignition Control Recommendations

- Use appropriate electrical equipment and wiring methods;
- Control static electricity, including bonding of equipment to ground;
- Control smoking, open flames, and sparks;
- Control mechanical sparks and friction;
- Use separator devices to remove foreign materials capable of igniting combustibles from process materials;
- Separate heated surfaces from dusts;
- Separate heating systems from dusts;
- Select and use industrial trucks properly;
- Use cartridge-activated tools properly; and
- Use an equipment preventive maintenance program.

Injury and Damage Control Methods

- Separation of the hazard (isolate with distance);
- Segregation of the hazard (isolate with a barrier);
- Deflagration isolation/venting;
- Pressure relief venting for equipment;
- Direct vents away from work areas;
- Specialized fire suppression systems;
- Explosion protection systems;
- Spark/ember detection for suppression activation;
- Develop an emergency action plan; and
- Maintain emergency exit routes.

Applicable OSHA Requirements Include:

- §1910.22 Housekeeping
- §1910.307 Hazardous Locations
- §1910.1200 Hazard Communication
- §1910.269 Electric Power Generation, Transmission and Distribution (coal handling)
- §1910.272 Grain Handling Facilities
- General Duty Clause, Section 5(a)(1) of the *Occupational Safety and Health Act* (Employers must keep workplaces free from recognized hazards likely to cause death or serious physical harm).

Resources

Readily available from www.osha.gov are:

- Combustible Dust National Emphasis Program
- Safety and Health Information Bulletin (SHIB) (07-31-2005) *Combustible Dust in Industry: Preventing and Mitigating the Effects of Fires and Explosions*

See the SHIB or www.osha.gov for other applicable standards.

The primary National Fire Protection Association (NFPA) consensus standards related to this hazard are:

- NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids
- NFPA 61, Standard for the Prevention of Fires and Dust Explosions in Agricultural and Food Processing Facilities
- NFPA 484, Standard for Combustible Metals
- NFPA 664, Standard for the Prevention of Fires and Explosions in Wood Processing and Woodworking Facilities
- NFPA 655, Standard for the Prevention of Sulfur Fires and Explosions
- See www.nfpa.org to view NFPA standards.

This is one in a series of informational fact sheets highlighting OSHA programs, policies or standards. It does not impose any new compliance requirements. For a comprehensive list of compliance requirements of OSHA standards or regulations, refer to Title 29 of the Code of Federal Regulations. This information will be made available to sensory-impaired individuals upon request. The voice phone is (202) 693-1999; teletypewriter (TTY) number: (877) 889-5627.

For assistance, contact us. We can help. It's confidential.

OSHA® Occupational Safety and Health Administration

www.osha.gov (800) 321-OSHA (6742)

U.S. Department of Labor

DSG 12/2014

What is Accreditation and Why it is Important

Sharon F. Webb, Ph.D.,
Director of Quality Assurance Program

Accreditation is the process that a certifying body declares that an entity or person is competent to perform a specific task or procedure according to a certain standard. Laboratories may become accredited for specific test methods or even calibrations that they perform. At the Division of Regulatory Services our Feed and Fertilizer Laboratory will be working towards accreditation to the ISO/IEC 17025:2005 Standard that is recommended for all state feed laboratories according to the Animal Feed Regulatory Program Standards (AFRPS). This will be a long and complicated journey for all of us in the laboratory and I thought you as our audience would find it interesting. Therefore, I'll be writing a series of articles that discusses various portions of the standards and how we meet those qualifications.

ISO stands for International Organization for Standardization, and is an independent, non-governmental membership organization. It is the world's largest developer of voluntary International Standards. It is made up of 162 member countries that are the national standards bodies around the world. These standards are documents that specify details for products, services, and systems to ensure quality, safety, and efficiency. They are a key factor in facilitating international trade. This organization has published over 19,500 international standards that cover almost every industry, from technology, to food and feed safety, to agriculture and healthcare. ISO has 3,368 technical bodies, or technical committees, that are made up of experts in that field from all over the world.

The Association of American Feed Control Officials (AAFCO) is a voluntary membership association of local, state, and federal agencies charged by law to regulate the sale and distribution of animal feeds and animal drug remedies. This organization has no regulatory authority, but works to provide a level playing field of commerce for the animal feed industry, ensure consumer protection, and safeguarding the health of animals and humans. I am on several national AAFCO committees and workgroups, and as part of my assignment representing our Division and/or AAFCO, I've learned quite a bit about the accreditation process. The first thing that a laboratory must do in order for the process to be successful is to ensure that the senior management is on board with the idea. The process of achieving the ISO/IEC 17025:2005 accreditation will be costly both in efforts, resources, and personnel, so without their support we would not even be able to get started! The next item on our check list is to purchase a copy of the standard. We currently adhere to the American Association of Feed Control Officials Quality Assurance/Quality Check Guidelines 2007. These guidelines have been updated to align the protocols and recommendations to each sub clause in the ISO standard and were published in 2014.

The next item on our to-do list is to do a "gap" analysis. A gap analysis is when you compare what policies and procedures you are using currently (2007 AAFCO QA/QC Guidelines) to what policies and procedures you want to put in place (2014 AAFCO QA/QC Guidelines). This is something that we are in the process of doing. We have already done the gap analysis to determine if our laboratory meets the AFRPS laboratory standard and discovered we only need to put into place a few things to completely meet that standard. The gap analysis to determine how our processes we currently use compare to what is required in the ISO standard is quite a bit more detailed oriented and requires significantly more documentation and paperwork. The fourth item on our checklist is having a clearly defined Quality System Manual (QSM) in place. This is a huge document that defines documents, records, traceability, contracts, purchases, complaints, and control over various actions that the laboratory may take and how they enact them. In other words the QSM will document our policies used in our organization, our standard operating procedures for everything including our analytical methods we use in the laboratory. This is something that we are currently working on as well.

The Management System Document Structure is made of the QSM, organizational and method procedures, data recording forms, and work instructions. This system will document how our organization is managed, confidentiality, and ethics policies and procedures. It also defines our relationship to our customer, which is defined as the Regulatory Program. We will develop a contract with the customer, and define procedures for reviewing the contract and sampling agreement with the customer. If we choose to out-source any analytes we will develop a sub-contract with the providing laboratory. In this document we will define our procedures for purchasing chemicals and equipment, handling non-conforming results and complaints, and define our preventative and corrective actions. Something else that is a key element in this whole process is auditing. We will have procedures for how to do our own internal audits. Of course, we will develop a policy to ensure document control is done, management reviews and build in a process to increase our overall quality.

The technical procedures will include how we train and evaluate our professional personnel and the conditions in which they work. Our analytical methods contain the suitability of the method for the specific analyte, method validation, and verification that demonstrates that the analytical method works as expected. Another undertaking that we will be developing is measuring uncertainty and traceability in each analytical method. This is very similar to the way the analytical variations are developed in the AAFCO Proficiency Program and published in AAFCO's Official Publication. Do not confuse "error" with "uncertainty". Error is defined as the

difference between a found value and a true value that are from mistakes or uncontrolled factors. Uncertainty is a measure of "sureness" about a found value. As a regulatory laboratory, we want both errors and uncertainty to be as close to zero as possible, but realistically it isn't possible. To measure the uncertainty, we have to closely examine and evaluate data and design the experiment, including sampling by our inspectors and subsampling in our laboratory, to minimize any inherent errors so that our uncertainty decreases. This is why all of our personnel, inspectors, lab techs, research analysts, supervisors, and directors, are well-trained and why we put into place so many quality checks, to increase the confidence in the values that we find for the analytes. In each analytical method that we use in our laboratory, we use quality reference material and/or NIST standards that have statistical data for us to compare our results. I'm sure you all know that when our inspectors take a sample they send it to Lexington, then a few weeks later you get a report of analytical values for certain analytes. What you may not realize is what we do in the laboratory when the sample arrives. We call this "Sample Handling". Upon receipt of a sample, we have procedures in place on how to track it from the sampling site to when the results are reported out. This will include sample receipt, chain-of-custody (for tracking the time the sample is taken until we receive it in our building), splitting and grinding of the sample, sample history (to document who has access to the sample and who has touched the sample), preparing a test sample, and storage of the sample. Sample handling and preparation is really one of the most important sources of error. However, our staff are highly trained and use statistically proven methods for handling the wide variety of the sample types our inspectors take. All of these procedures and policies will be documented under this heading.

The ISO/IEC 17025:2005 standard also dictates what is on the final report. Over the next few years, the report will change to include the details that ISO/IEC require.

As we progress towards ISO/IEC 17025:2005 accreditation, I will continue to update you. We are committed to maintaining the high-quality services we provide and will add analytical methods to our repertoire that will benefit the people of the Commonwealth. We will continue to provide our Regulatory Programs unbiased and accurate results in a timely manner.

Regulatory Services Personnel Changes

New Employee

Catherine (Cate) Perkins started work on June 1 in the Seed Germination Lab. She replaces Beth Nichol who retired in May. Cate is originally from Abingdon, Virginia and earned a B.S. in Horticulture from Virginia Tech and an M.S. in Public Horticulture from the University of Delaware. She spent a little over 3 years working with the Peace Corps in Cameroon after graduation. Cate was working at Wilson Nurseries in Frankfort prior to joining Regulatory Services.
Cate and her husband Andrew live here in Lexington where he is working on a graduate degree in music theory. She is another strong addition to our team and we are glad she has joined us.

Updates on Food Safety Modernization Act
Dr. Alan Harrison – Director Feed and Milk Programs

The Food Safety Modernization Act (FSMA) Preventative Controls for Animal Food rule is now final and is scheduled to be published on September 17, 2015. With the publishing of the final rule, this means that some businesses will need to be in compliance by September 2016.

For nearly 2 years, the Food and Drug Administration (FDA) has considered comments from industry, consumer groups, academia and other stakeholders and has revised the original rules with those comments in mind. Here's a condensed version of what's coming down the road with FSMA for the feed industry.

Current Good Manufacturing Practices (cGMP's) have been established for animal food (or feed) production. If a processor already implements human food safety requirements, additional controls are not required if there is no further processing of the product. For example, a distillery should not need to implement animal feed cGMP's to distribute wet distillers grains, but would be subject to implementation of preventative controls if they dried spent grains and distributed dried distillers grains.

Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The written food safety plan must include hazard analysis, preventive controls, oversight and management of preventive controls (monitoring and verification), and a recall plan.

An animal food manufacturing/processing facility must have a risk-based supply chain program for those raw materials and other ingredients for which it has identified a hazard requiring a supply-chain-applied control. If an identified hazard will be controlled by another entity in the distribution chain, a facility would not be required to implement a preventive control.

Operations meeting the definition of 'farm' are not subject to the preventive controls rule. A Primary Production Farm is defined as an operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. A Secondary Activities Farm is an operation not located on the Primary Production Farm that is devoted to harvesting, packing, and/or holding raw agricultural commodities. The secondary activities farm definition has very limited application to animal food beyond grain storage.

Feed mills associated with farms (vertically integrated operations) not covered. Under the new rules, if the feed mill, animals, land, and establishment are all owned by the same entity, this meets the definition of a farm and are therefore not subject to the Preventive Controls for Animal Food final rule. We can expect a future FDA ruling that will require some feed mill operations that currently are part of a farm to implement the current good manufacturing practices established by the Preventive Controls for Animal Food rule.

Compliance Dates: Businesses will have a staggered number of years after publication of the final rule to comply, based on business size. In addition, there will be staggered compliance between the CGMP requirements and the Preventive Control Requirements. This was one area of the proposed rules that generated much discussion and comments. The intent of this staggering of compliance dates appears to be to get the largest feed mills in compliance quickly while allowing the businesses with more limited resources a reasonable time to make necessary changes. These are the categories of business size in the final rule.

Business Size	CGMP compliance date	PC compliance date
Business other than small and very small	1 year	2 years
Small business (a business employing fewer than 500 full-time equivalent employees)	2 years	3 years
Very small business (a business averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).	3 years	4 years, except for records to support its status as a very small business (January 1, 2017)

FDA clearly recognizes that there will be a great deal of industry education required with these new regulations. We can expect to see guidance documents in the near future covering CGMP requirements, hazard analysis and preventive controls, human food by-products for use as animal feed, and a small entity compliance guide.

To learn about this subject, try this link: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm

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