Regulatory Services News

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Director's Digest

Regulations Update

The revised regulations covering both commercial livestock feed and pet food have passed all legislative hurdles and are now technically in effect. I say technically because while the pet food regulations became effective on 9-28-2018 and the commercial feed regulations on 10-11-2018, we will delay implementing all changes until everyone has had a chance to review them. We are in the process of having these printed up in booklet form which our inspectors will have available to distribute. The revised regulations have been placed on our website and we hope to have a feed advisory board meeting to review them in the near future. This has been a long process and we are glad to have our feed regulations updated for the first time since 1999. There will be some changes in required labeling so I urge you to become familiar with them as soon as possible. We will be happy to email you a PDF of the regulations if you get in touch with us.

Moving Science Forward

By the time you read this, the 2018 elections will be over and I hope each of you took the time to vote. We had some hotly contested races in central Kentucky and I don't know when I have ever become sicker of seeing political ads on television.

I recently read an article by a Canadian blogger pointing out the importance of electing the proper people if we want science to move forward and develop the technology to allow us to feed the rapid population growth we expect in the next 30 years. Stuart Smyth is on the faculty at the University of Saskatchewan and shares how political decisions have destroyed innovation in Europe when it comes to food production. He points out that in 2002, Europe established a new regulatory agency, the European Food Safety Authority (EFSA) to resolve its regulation problems regarding GM crops and other food safety challenges. Unfortunately, instead of evaluating products created by GM technology they assess the risk of the process used to create GM crops. While EFSA evaluates the risk assessment, the approval of GM crops is a political one made by the Standing Committee on Plants, Animals, Food and Feed of the European Commission. Since 2002 the Standing Committee has approved only one GM crop variety for production which was a GM potato developed by BASF. It took 13 years to receive

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approval of the GM potato and the technology was outdated by then so BASF decided not to sell the product in Europe. The inability of the EU regulatory system to approve GM crops in a timely manner led BASF to move all of its plant biotech research to North and South America which resulted in a loss of up to 900 scientific jobs.

Compare this to Canada which has approved 85 new GM varieties since 2002. The difference is that Canada regulates the product that will enter the market and doesn't differentiate on what process was used to create the product. Canada regulates the what, not the how, while the EU has the holdup issue of how it's produced. The decision in Canada is also made by a regulatory agency and not a political committee of the government. If the new GM product is no riskier than those products already available, then it is deemed to be scientifically equivalent and is approved for production. This method evaluates all relevant risks in a timely and efficient manner. This has resulted in approval of 119 GM products in Canada since the first one in 1995 and no environmental or human health risks have occurred.

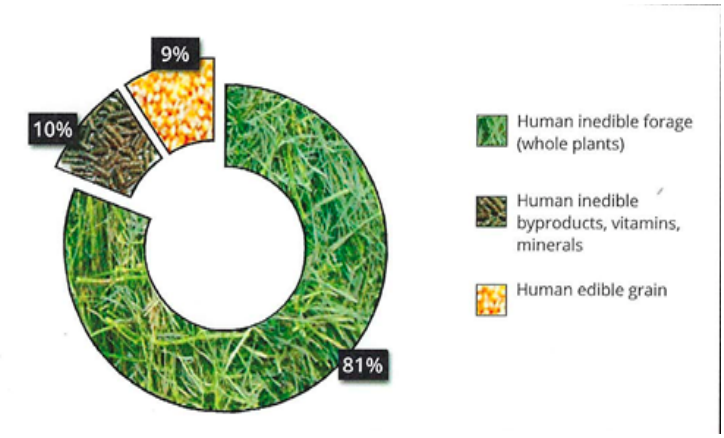
Whether or not you believe in utilizing GM crops and I certainly respect your right to choose, the big loss of the decisions in Europe is in human capital. Restricting technology development in Europe is resulting in many of their young scientists moving to the America's to continue doing research no longer possible in the EU. Dr. Smyth points out that "with professors, graduate students and research scientists all seeking to relocate to America and other jurisdictions where cutting-edge science is allowed to proceed without stifling regulations, the 'brain drain' on Europe will be staggering."

Think of the improvements in food production that have occurred in the U.S. over the last 50 years as a result of university and private research plus the role the extension service has had in disseminating information. We in agriculture need to make our voices heard and support those politicians who promote and incentivize the research needed to feed the world. We won't be able to feed the population in 2050 with 1950 (or even 2018) technology.

Beef Cattle as Upcyclers

Recycling has been a popular trend for a number of years and one I strongly support. Recently, Sara Place with the National Cattleman's Beef Association gave a presentation on the sustainability of beef and put forth the argument that beef cattle should be considered upcyclers. Upcycling is defined as "the process of transforming by-products, waste materials, useless, or unwanted products into new materials or products of better quality or for better environmental value." When you consider that cattle take something we can't digest such as grass plus use byproducts from other industries such as corn gluten feed and distillers grains to make nutritious beef this is a strong argument.

There are many who advocate that cattle production should be eliminated and the grain they consume should be diverted for human food (although I doubt many of us would want to eat field corn). The graphic below shows the amount of grain that cattle actually consume during the course of their life:



As this graphic shows, more than 90% of what grain finished beef cattle eat is not in competition with the human food supply. The corn fed to cattle represents 2% of U.S. cropland acres or 0.3% of total U.S. land area.

Beef critics will also point to the pounds of feed it takes to produce a pound of beef compared to pork or chicken. This is pointed out by the first column in the table shown on the next page:

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	Pounds of feed per pound of product, live weight	Pounds of human-edible feed (e.g., corn, soy) per pound of product, live weight	Net protein contribution** (values > 1 mean more high quality protein generated than used)
***U.S. average grain-finished beef** (full life cycle)** 	13.8	1.6	2.53
***Broiler chicken** (Avigen ROSS 308 @ 40 days)* 	1.6	1.4	0.85
***Pork** (Wilkinson, 2011)* 	2.5	2.0	0.70

*From Rotz et al., unpublished data under review **Using DIAAS from Ertl et al., 2016

When you just look at total feed to pound of product, certainly 13.8 pounds versus less than 3.0 pounds doesn't bode well for beef but as Paul Harvey used to say: "now for the rest of the story" (yes I know I have dated myself by quoting Paul Harvey). Remember that 91% of the diet of a finished beef is not from "human edible" feed. When you take this into account in column 2 you see that beef is very comparable to chicken and pork in feed efficiency. Column 3 portrays the quantity and quality of protein produced by each species in comparison to the human quality protein consumed and beef is the only product with a value greater than 1. This supports that cattle are acting as "upcyclers" in our food system: rather than simply recycling, cattle are upgrading human inedible plant proteins and food waste into high quality protein and essential micronutrients, such as B-vitamins.

With many companies trying to produce plant based meats, Sara offers the following food for thought: "The beef community uses a technology that produces high-quality protein from solar energy locked within human inedible plants. The technology produces a natural organic fertilizer, and is mobile without using fossil fuels. The technology self-replicates. The technology is cattle. Beef is the original plant-based meat."

Share some food facts with your Thanksgiving guests

When you gather with family and friends for Thanksgiving meals, take the opportunity to share some food facts about Thanksgiving staples with those less familiar with agriculture such as:

- Turkey – Minnesota is the top producing turkey state and American farmers produce more than 253 million turkeys each year, and over 46 million (18%) of those are eaten on Thanksgiving.
- Domesticated turkeys cannot fly. Wild turkeys fly for short distances up to 55 miles per hour and can run 25 miles per hour.
- Potatoes – The U.S. produces nearly 50 billion pounds per year with Idaho and Washington being the top producing states.
- Cranberries – The top cranberry growing states are Wisconsin, Massachusetts, New Jersey, Oregon and Washington. Only 5% of cranberries are sold fresh, the remainder are sold as juice, sauce, etc. Similar to turkeys about 20% of yearly cranberry production is consumed at Thanksgiving.
- Green beans- About 1.5 billion pounds are produced each year with Wisconsin, again, leading in production.
- Pumpkin – Fifty million pumpkin pies are eaten on Thanksgiving and the U.S. produces 1.5 billion pounds of pumpkins each year. Illinois leads in production, followed by Indiana, Ohio, and Pennsylvania.

Dr. Darrell Johnson
Executive Director

What is an Official Sampling Method?

Back in September, I was asked to present at the annual Basic Inspector Training Seminar (BITS) held in Harrisburg, PA. This is a joint training presented by the Association of American Plant Food Control Officials (AAPFCO), Association of American Feed Control Officials (AAFCO) and the Association of American Seed Control Association (AASCO). Our Division is a member of all three of these associations and is very active on committees and in leadership roles. BITS is held each year across the country with an aim to teach agricultural inspectors proven methods for obtaining samples for their Feed, Fertilizer and Seed Programs.

The BITS agenda reviews inspector Professionalism, Biosecurity, Safety, Feed and Fertilizer Labeling, Best Manufacturing Practices for fertilizer, AAFCO Good Manufacturing Practices (GMP) Checklist, as well as sampling techniques. This years' training included inspectors from over 20 states and instructors from AR, IN, KY, MO, NC, PA, and TN. One day of the training is set aside for sampling demonstrations at a local feed mill, fertilizer manufacturer and seed distributor. During this day of training the participants get a hands-on approach of how to sample and review labels. The procedures discussed have been around for many years as AOAC procedures. AOAC is the Association of Official Agricultural Chemists, this organization has since had a name change and was actually the start of AAFCO and AAPFCO.

All of our Divisions regulatory inspectors have taken the BITS training at some point in their career. This is just one part of their training program. For feed and fertilizer samples, at least 10 subsamples of a product are obtained to create our sample used for analysis. Seed has a different set of standards which is to sample at least 5 subsamples plus 10% of the lot, not to exceed 30 subsamples to create the sample used for analysis. Our Division purchases one package for small package products for analysis. The tools used to obtain our subsamples are AOAC approved sampling triers or a modification in order to cover all of the different products we sample. The general theory for sampling triers is that the triers opening must be wider than the longest particle we are sampling. Most of the triers we use have a ¾ inch opening but we also have smaller triers for sampling small particles like clover seed.

We do not take lightly the procedures used to obtain samples and emphasis is given to obtain all samples via a recognized method. The same is true for when the samples arrive in our laboratory for analysis, but this would be a discussion for another newsletter. If you have any questions on our sampling techniques please call our office.

Steve McMurry
Director of Fertilizer and Seed Programs

Renovation of Soils Lab in Princeton

Soil testing in our department is conducted by laboratories in Lexington and Princeton. About 24,000 samples per year are tested in Lexington and about 16,000 samples per year are tested in Princeton. The lab in Princeton is undergoing renovation in the spring as part of the development of the Grain and Forage Center of Excellence.

The Princeton lab will be vacating their current location and moving to a temporary location from the end of January until June. Princeton will be without an important instrument for testing during the interim period and will utilize the instrument in the Lexington lab. The renovation will thus affect turn-around time in both labs as all samples are analyzed by the instrument in Lexington.

County Extension Offices have been notified to encourage fall sampling as much as possible to ease the number of samples received in spring to lessen the impact on turn-around time. If you have soil needing tested, sampling in the fall will ensure you get results early for planning fertilization in the spring.

Patience and understanding as we manage in this transitory phase is greatly appreciated. We are looking forward to an improved lab in Princeton after the renovation to continue quality service to our customers in western Kentucky.

Dr. Frank Sikora
Director of Laboratories

Feed Facility Inspections under Food Safety Modernization Act Regulations – Part 3

In previous newsletters, I presented an introduction to feed facility inspection under The Food Safety Modernization Act (FSMA) and reviewed the first 4 sections of 21 CFR Part 507 Good Manufacturing Practices (GMP's). With a final compliance date for Good Manufacturing Practices of September 17, 2018, all facilities, regardless of size, that

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manufacture, process, pack, or hold animal food will need to comply with these GMP regulations now. Under our inspection contract with FDA, our inspectors will conduct 24 GMP inspections under FSMA regulations (21 CRF Part 507) this fall and winter. Firms manufacturing medicated feed will be familiar with GMP inspections focusing primarily on the use of medications. The new regulations are not limited to medicated feed and include language that applies to both manufacturers and distributors.

The 8 sections in 21 CFR Part 507, Subpart B are: 1) Personnel, 2) Plant and grounds, 3) Sanitation, 4) Water supply and plumbing, 5) Equipment and utensils, 6) Plant operations, 7) Holding and distribution, and 8) Holding and distribution of human food by-products for use as animal food. This article will address the last 4 sections. This is my condensed version of the regulations, the compliance areas where our inspectors will focus, and expectations.

Equipment and utensils – 21 CFR 507.22

- All plant equipment and utensils designed and constructed to be adequately cleanable, and are properly maintained.
- Holding, conveying, manufacturing, and processing systems are designed, constructed, and maintained to protect against feed contamination.
- Instruments and controls used for monitoring temperatures, pH, water activity (aw), or other conditions that control/prevent growth of undesirable microorganisms are adequate.

Plant operations – 21 CFR 507.25

General

- Management ensures that all operations are meeting cGMP requirements, animal feed is accurately identified, and packaging materials are safe and suitable.
- Overall cleanliness of plant is under supervision of competent individual(s) with assigned responsibility.
- Adequate precautions are taken so that plant operations do not contribute to contamination of animal food including minimizing growth of undesirable microorganisms.
- Animal feed that has become adulterated is handled in a manner that protects against contamination of other feed.
- Testing procedures are used where necessary to identify sanitation failures or possible animal food contamination.

Raw materials and other ingredients

- Raw materials and other ingredients are suitable for use in animal feed and handled to protect against contamination and minimize deterioration.
- As necessary, raw materials are cleaned to minimize contamination and stored to protect against contamination and deterioration.
- Ingredients susceptible to contamination with mycotoxins or other natural toxins are evaluated and properly used to prevent injury or illness to animals or humans.
- Frozen ingredients are kept frozen. If thawing is required, it is done to minimize the potential for growth of undesirable microorganisms.

Manufacturing, processing, packing, and holding operations

- Animal feed is maintained under conditions to minimize growth of undesirable microorganisms and prevent the animal food from becoming adulterated.
- Measures taken to minimize/prevent growth of undesirable microorganisms adequately to prevent adulteration.
- Work-in-process and rework are handled to protect against contamination and growth of undesirable microorganisms.
- Manufacturing processes are performed in a way that protects against the contamination of animal feed.
- Packaging operations are performed in a way that protects against the contamination and growth of undesirable microorganisms.
- Feed that relies principally on control of water activity (aw) for preventing the growth of undesirable microorganisms is processed to and maintained at a safe aw level.
- Feed that relies principally on the control of pH for preventing the growth of undesirable microorganisms is monitored and maintained at the appropriate pH.
- If ice is used in contact with animal food, it is made from water that is safe and manufactured in accordance with cGMP as outlined in this subpart.

Holding and distribution – 21 CFR 507.27

- Feed held for distribution is protected against contamination and deterioration in appropriately constructed containers that are cleanable and maintained.

- Labeling contains information and instructions for safely using the product for the intended animal species.
- All shipping containers and bulk vehicles used to distribute animal food are examined prior to use to protect against the contamination of animal food.
- Animal food returned from distribution is assessed for animal food safety to determine the appropriate disposition and is properly identified and segregated until assessed.
- Unpackaged or bulk animal food is held in a manner that does not result in unsafe cross contamination with other animal food.

Holding and distribution for human food by-products – 21 CFR 507.28

- Human food by-products held for distribution is protected against contamination and deterioration in appropriately constructed containers that are cleanable and maintained.
- Labeling by common or usual name accompanies human food by-products when distributed.
- All shipping containers and bulk vehicles used to distribute human food by-products are examined prior to use to protect against the contamination of animal food.

The first 4 sections of subpart B, discussed in the previous article, focus more on the facility while the last 4 sections are more related to manufacturing activities. As mentioned in the earlier articles, FDA has structured these regulations to provide flexibility in meeting these requirements.

In our next newsletter, I will summarize the 8 sections of subpart B and review record keeping requirements (subpart F) of the Part 507 Good Manufacturing Practices.

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

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

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

Dr. Alan Harrison
Director of Feed and Milk Programs

Inspector News

It is with sad news that I relate the passing of Noel Johnston from Hart County this past August. He was a retired inspector from Regulatory Services and worked as an inspector for over 38 years.

Our inspection staff continues to attend FDA trainings to learn about all the new FDA FSMA inspections. In August, Bart Young, Nathan Keith, Warren Pinkston and I attended the FDA VM102 training in Minneapolis for the Title 21 CFR Part 507 cGMP feed mill inspection. Brad Johnston attended this course in Omaha in October. All 8 of our field inspectors in addition to me have now been through this course for part 507 cGMP inspections.

It is time of year for the contract FDA feed mill inspections. This year our contract is for: licensed medicated feed mills, non-licensed medicated feed mills, BSE inspections, VFD inspections and new this year is the cGMP part 507 feed mill inspections for all firms including those that do not make medicated feed.

So the new Title 21 CFR Part 507 is for all firms that manufacture feed of any kind. This is the part of the new FSMA law that requires feed manufacturing firms to have a written food safety plan.

There are 8 parts that make up the cGMP Part 507 inspection (these have been covered in detail by Dr. Harrison's articles in this and the past 2 issues of Regulatory Services News):

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

The records required for the cGMP 507 inspection are related to training of employees that work in the feed mill related to the above 8 parts of the cGMP.

If you have questions about any of the requirement of the cGMP part 507 inspection or would like to walk through your feed mill and discuss the requirements of the 507 inspection, please talk to your inspector.

Jim True
Inspection Program Coordinator

What Changed in the Commercial Feed and Pet Food Regulations?

As noted in the Director's Digest, the revised commercial feed and pet food regulations are now in effect. Many of you may want to know what changed without having to sit down and compare the old to the new and we will summarize the major changes in the table below. The regulations for our Feed Program were last updated in 1999 so we were certainly due for a revision. There are no changes in fees as these are set in the law instead of in the regulations.

The American Association of Feed Control Officials (AAFCO) has put forth a model bill and regulations and encourages all states to adopt this to make it easier for businesses to conduct commerce in multiple states. This model bill has been endorsed by the American Feed Industry Association, National Grain and Feed Association, and Pet Food Institute. Part of our update was to make our regulations more in line with this model bill.

Kentucky legislative rules will not allow for referencing the "most recent" edition of a set of guidelines so you must reference a particular year. Our previous regulations reference the 1996 Official Publication (OP) of AAFCO, this has been updated to the 2018 OP for these revised regulations.

Commercial Feed Regulations

Regulation	Old Title (New Title)	Changes
12 KAR 2:006	Definitions	Updated OP Reference.
12 KAR 2:011	Label format	No changes.
12 KAR 2:016	Brand and product Names	Added raw milk reference.
12 KAR 2:017	Product purpose statement	Removed Direct Fed Microbial reference to place elsewhere.
12 KAR 2:018	Guaranteed analysis	Added option for maximum ADF (in place of crude fiber) for multiple species; maximum ADF and NDF required for equine feeds; updated equine animal classes; separate sheep and goat requirements with maximum ADF required for goats; updated OP reference.
12 KAR 2:021	Guarantees (title changed to Expression of guarantees)	Added mineral phosphatic materials; added section on dietary starch, sugars and fructans; added reference to Analytical Variation table to determine violations; Direct Fed Microbial reference moved here.
12 KAR 2:026	Ingredients	Removed Section 8 (Rice Hulls) and Section 9 (Magnesium BV); updated OP reference.
12 KAR 2:031	Directions and precautionary statements for feed containing additives (title changed to Directions for use and precautionary statements).	Added required labeling for feeds containing raw milk.
12 KAR 2:036	Non-protein nitrogen	Added language required on labeling for feeds containing non-protein nitrogen.
12 KAR 2:041	Drug and feed additives	Modified language to match AAFCO model bill; updated OP reference.
12 KAR 2:046	Poisonous or deleterious substances	Added statement about deleterious substances "not limited to" the ones listed.
12 KAR 2:051	Manufacturing conditions	Modified language to match AAFCO model bill including references to FSMA regulations.
12 KAR 2:056	List of manufacturers	Instead of purging files on January 1 of each year, list of manufacturers will be evaluated quarterly and removed as needed
12 KAR 2:061	Registration	Updates "Application for Registration of Commercial Feeds" from March 1999 version to 2018 version.
12 KAR 2:066	Suitability	Updated NRC references to the most current versions.

Pet Food Regulations

Regulation	Old Title (New Title)	Changes
12 KAR 3:007	Definitions and term	Added "specialty pet food", "all life stages", "family".
12 KAR 3:012	Uniform labeling format (changed to Label format and labeling)	Multiple changes to match AAFCO model bill including a table on Minimum Warning Statement Type Size. Updated OP reference.
12 KAR 3:017	Brand and product names	Multiple changes to match AAFCO model bill including table on type size.
12 KAR 3:022	Guarantees (title changed to Expression of guarantees)	Multiple changes to match AAFCO model bill including table on type size.
12 KAR 3:027	Ingredients	Qualifications for using the terms "meat" or "meat byproducts"; updated OP reference.
12 KAR 3:028	Descriptive terms	New regulation dealing with terms such as "lite", "less fat", "reduced carbohydrates".
12 KAR 3:032	Directions for use (title changed to Feeding directions)	Added sections on labeling products as "complete and balanced"; foods labeled to be fed under veterinary supervision; updated OP reference.
12 KAR 3:037	Additives (title changed to Drugs and feed additives)	Main change was to add the term "specialty pet food" and updated OP reference.
12 KAR 3:039	Nutritional adequacy	New regulation spelling out the intended usages of the pet food such as "all life stages".
12 KAR 3:042	Statement of caloric content (title changed to Statements of calorie content)	Statement of calorie content is required for all dog and cat snacks, treats, and foods. Defines how "calorie content" statements should appear. Updated OP reference.

The intent of these tables is just to provide a quick overview of changes made in the regulations. Pet food regulations have changed the most since the last revision. The new regulations are now available on our website (www.rs.uky.edu) and we encourage you to become familiar with these as soon as possible.

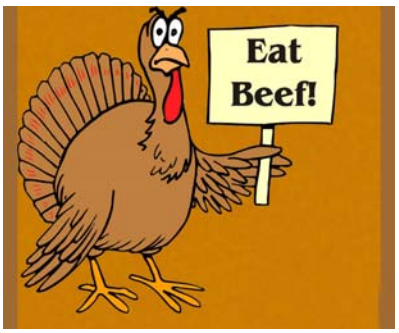
Dr. Darrell Johnson
Executive Director

Upcoming Meetings

AAFCO Midyear Meeting
January 21-23, 2019
Hyatt Regency
Savannah, GA
https://www.aafco.org/Meetings

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

HAVE A GREAT THANKSGIVING, MERRY CHRISTMAS AND HAPPY NEW YEAR!



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