

Regulatory Services News

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

Winter 2022

Director's Digest

Animal source foods in healthy, sustainable and ethical diets

I respect everyone's right to eat what foods they know or feel are best for their health but do not appreciate it when others try and tell me what I should consume. As someone who has spent their entire life raising livestock and consulting with others who do, I am especially offended when some imply that animal source foods have no place in modern diets. Animal Journal recently published a board invited review entitled "Animal source foods in healthy, sustainable, and ethical diets – An argument against drastic limitation of livestock in the food system." I will highlight a few key points from a fifteen-page article.

During the last decade, voices to reduce or eliminate animal source foods from our diet have become louder and louder. They argue that animal source foods cause harm to (1) human health, (2) the planet, and (3) the animals. The authors present arguments against each of these claims and propose that policy makers would be better off tackling (1) nutrient deficiencies and over-consumption of energy-rich, nutrient-poor, and ultra-processed diets, (2) the excessive use of fossil fuels and hyper-extractive

business models, (3) the lowering of environmental impacts of all forms of crop and animal agriculture and (4) the urban disconnect with the rural food chain.

Animal source foods in healthy diets

Overconsumption of almost any food can be bad for your health and animal foods are no exception. Too much steak, bacon, eggs, or cheese can contribute to health issues but humans by nature are omnivores and animal source foods provide a dense and available source of many nutrients that are not as well provided by plant sources. As covered in an earlier Director's Digest, lack of animal source foods in the diets of infants and children hinder both their physical and mental development. Four out of eight food groups contributing to the World Health Organization minimum dietary diversity score for children are of animal origin. Without supplementation, those on a strict vegan diet are more likely to be deficient in Vitamins A, B₁₂, and D, plus calcium, iron, zinc and other key nutrients. The chart on the next page shows the portion size needed to achieve an

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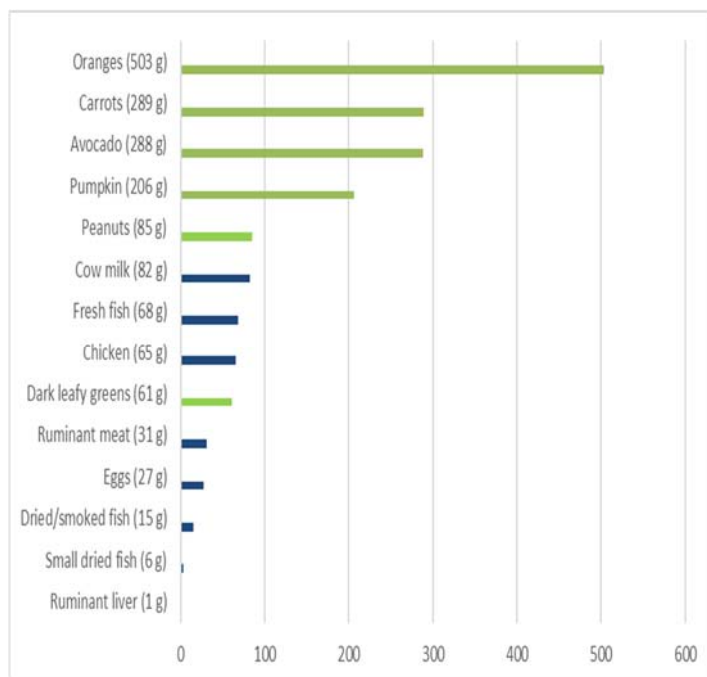
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average of 33.3% of the requirements for iron, vitamin A, zinc, folate, vitamin B12, and calcium.



I'm not a fan of pumpkin or avocado, but love oranges, carrots, and peanuts. However, this chart emphasizes to me that to balance my diet, I also need to drink milk and eat some eggs or meat. If not, I need to find a supplemental source of nutrients.

Animal source foods in sustainable diets

A commonly heard argument is that animal feed competes with crops that would otherwise be directly suitable for the human diet. While this is partially true, it doesn't present the whole picture. Exaggerated estimates claim that 6-20 pounds of grain are required to produce 1 pound of meat, while in reality this is around 3 pounds of grain. More importantly, it should be noted that 86% of livestock feed includes forage, crop residues, and by-product feeds (such as distiller's grains, soyhulls, and corn gluten feed) that are not suitable for human consumption in the first place and would otherwise form an environmental burden. For ruminants, especially, only 5% of the global feed intake consists of grains and soybean meal that are in direct competition with the human diet. Because cattle's primary asset is to upcycle inedible materials to high-quality nutrition

based on their rumen metabolism, they function as net contributors to the production of human-edible protein worldwide. In fact, ruminants need less protein from human-edible feed (0.6 pounds) than what they deliver as one pound of human-edible, high-quality protein.

A reasonable case can be made for some of the cropland that is now used for feed production be shifted to grow crops for direct human consumption. However, calls allowing for further conversion of pasture ground into cropland are short-sighted to existing examples of ecosystem damage and loss of wildlife habitat. For example, in the US alone, over a million acres/year of native grasslands have been converted to croplands between 2008 and 2016, with nearly 70% of these new croplands producing yields below the national average at the detriment to bird-life. The best land for growing crops is already in production.

Great strides have been made in the last twenty years to make animals more efficient in the amount of feed and water used to produce meat, milk, and eggs. Improvements are also being made in reducing their contributions to greenhouse gases. There is still work to be done and animal scientists continue to do the necessary research to make animal production more sustainable. It should also be considered how many people and cultures rely on animal production for their livelihood. The three components of sustainability are (1) environmental stewardship, (2) economic viability, and (3) social responsibility. The environmental impact of livestock needs to be assessed in relation to the alternative livelihoods for those populations that rely on livestock as the pathway out of poverty.

Animal source foods in ethical diets

Ethics represent standards of what is generally to be expected from each other and from ourselves in specific situational settings. There are advocates of doing away with all forms of animal production. They depict animal husbandry as an immoral system of "exploitation" that requires "liberation", rather than as one of sustenance and nourishment. Animal death will not be eliminated if livestock production is

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eliminated. What is often not considered is the number of animals that are killed as field deaths during crop production (via pest control, plowing, harvesting machines, etc.).

As an alternative to what is now often presented as exploitation, livestock farming can instead be viewed as a symbiotic relationship between humans and animals, to the benefit of both. This is only true when animal welfare standards are in place and livestock receive a dignified life and fast death. When compared to animals living in the wild, livestock animals receive shelter, are better fed during the winter, receive veterinary care, are protected from predators, and do not die after a long agony.

In conclusion, animal protein sources are an important source of human nutrition and can be part of a healthy, sustainable, and ethical diet. Choosing to live a vegan lifestyle is a personal choice and with proper nutrient supplementation is certainly feasible. Animal husbandry is a historical component of many cultures and a way out of poverty for many. Hopefully, policy makers will concentrate on how both plant and animal foods can best meet the needs of our growing population going forward. Too many restrictions on either plant or animal production will not bode well for future generations.

Reference article is: "Animal Board invited review: Animal source foods in healthy, sustainable, and ethical diets – An argument against drastic limitation of livestock in the food system" Animal 16 (2022) 100457

Dr. Darrell D. Johnson,
Executive Director

Seed Registration and Permit Renewals for 2023

The renewal process for seed registrations and permits will occur over the next few months. Applications will be emailed or mailed to seedsmen, seed dealers, and seed conditioners who were permitted and registered in 2022.

Firms that sell seed at retail in container sizes of 40 pounds or more are required to register as Seed Dealers. Locations that condition uncertified seed for distribution in Kentucky are required to

register as Non-Certified Seed Conditioners. Those who condition only certified seed are registered as a part of the certification process under the Kentucky Seed Improvement Association.

Anyone who labels agricultural seed or agricultural seed mixtures is required to obtain a Permit to Label Agricultural Seed. Those who obtain this permit are also required to file Semi-Annual reports and pay fees based on the container size of the product. Semi-Annual reporting forms are emailed or mailed to agricultural seed permit holders at the end of each period and are required to be filed within 45 days after the end of each period.

Anyone who labels vegetable seed, flower seed, or combination mulch, seed and fertilizer is required to obtain a Permit to Label Vegetable Seed, Flower Seed, or Combination Mulch, Seed, and Fertilizer Products. These products are not subject to the Semi-Annual reporting schedule.

Fees for registrations and permits are \$25 each. Locations that are required to obtain both a labeling permit and a registration or both registrations only pay one \$25 fee for all. It is common for a location to be involved in conditioning seed, labeling seed, and selling seed at retail. All three applications are required, but only one \$25 fee is paid. A \$50 fee would only be required if both labeling permits are needed. The registration fees are waived if one or both permits are obtained.

Applications will be emailed or mailed to your location and are based on the applications that you currently have. Please complete the applications and return with the application fee stated to our office. If you have questions about this process, please contact Marilyn Smith at 859-218-2468 or mm.smith@uky.edu.

Stephen McMurtry,
Fertilizer and Seed Program Director

Inspections under Food Safety Modernization Act Regulations: A Review of Kentucky Experiences

As we enter our 6th year of inspections under the Food Safety Modernization Act (FSMA) regulations, it is a good time to review what we have learned and offer some advice to firms regarding what to expect from these inspections.

Our 2022-23 contract with FDA includes inspections at 32 Kentucky feed manufacturers. All of these inspections include compliance with Good Manufacturing Practices (GMP's) regulations covered under 21 CFR Part 507 Subpart B. Additionally, 12 of these inspections will include coverage of the Hazard Analysis and Risk-Based Preventative Controls (PC's) under 21 CFR Part 507 Subpart C. Medicated feed is produced by 16 of the firms on our list and our inspectors will also inspect for compliance with 21 CFR Part 225 at these mills.

Currently, our division has 7 inspectors trained to conduct these inspections. Our two newest inspectors will be trained in the coming months. For non-medicated feed mills under only the cGMP FSMA regulations, inspections should take a day or two at the most depending on the size for the operation and the products produced. If a medicated feed inspection is included along with a Part 507 cGMP, we will send 2 inspectors and they will spend at least a full day or two half-days inspection time including interviews and record review. The addition of the PC inspection may add another half day. Inspections that go well tend to go quickly. Those that do not always take longer.

In the last two years, our inspectors have conducted inspections at a total of 55 manufacturing facilities. All inspections have included the Part 507 cGMP regulations and 16 have included the Part 507 PC regulations. Of these 55 inspections, 25 were at medicated feed mills. For the purposes of this review, I will focus only on the discussion items noted by our inspectors that involve compliance with the Part 507 regulations. Please note that for brevity, these are my condensed versions of the regulations.

Subpart B – 21 CFR 507.14-507.28

Qualifications – 21 CFR 507.4

- Management ensures that all individuals involved in manufacturing, processing, packing, or holding animal food are qualified to perform assigned duties.
- A training program is in place and records of training maintained.

Training programs need not be overly complicated but must include proper documentation. Documentation should include training location, subject, date, identification of trainer, and initials or signatures of trainees. Outside vendors may also be sub-

ject to training. The most common discussion item noted by our inspectors involved a lack of proper documentation of the training program (507.4d).

Plant and grounds – 21 CFR 507.17

- Grounds around establishment plant under the control of the management are maintained to protect against the contamination of animal feed – free of litter and waste or conditions that may attract and harbor pests and adequately drained.
- The plant is suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control – adequate access, moisture control, ventilation, and lighting.
- Feed stored outdoors in bulk is protected from contamination by any effective means – protective covering and/or pest control protocols.

Specifically mentioned discussion items were failure to provide protection or control against feed contamination (507.17a) and failure to use shatter-resistant light fixtures (507.17b5).

Sanitation – 21 CFR 507.19

- Buildings, structures, fixtures, and other physical facilities of the plant are kept clean and in good repair to prevent animal feed from becoming adulterated.
- Feed-contact and non-contact surfaces of utensils and equipment are cleaned, maintained, and properly stored.
- Cleaning compounds and sanitizing agents utilized are safe and adequate under the conditions of use.
- Toxic materials in the plant area are properly identified and stored and limited to those required to maintain clean and sanitary conditions, necessary for use in laboratory testing procedures, necessary for plant and equipment maintenance and operation; and necessary for use in the plant's operations.
- Effective measures are employed to exclude pests from the feed manufacturing, processing, packing, and holding areas.
- Trash is conveyed, stored, and disposed to protect against the contamination of feed and minimizes the potential for trash to attract and harbor pests.

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Sanitation compliance issues were the second most common discussion item. Areas specifically mentioned were failure to keep facilities clean (feed spillage) and in good repair (507.19a) and failure to clean feed utensils (507.19b).

Plant operations – 21 CFR 507.25

General

- Management ensures that all operations meet 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.

The plant operations regulations cover a wide range of the feed manufacturing process. Observed compliance issues under this regulation: failure to label feed bins (507.25a2), failure to take adequate precautions when using non-feed equipment with feed processing (507.25a5), and inadequate clean-out procedures (507.25c4).

Subpart C – 21 CFR 507.31-507.55

Food Safety Plan – 21 CFR 507.31

- The plan must be prepared or overseen by a qualified individual(s).
- The written plan must include hazard analysis, preventative controls, supply chain program, recall plan, implementation monitoring, corrective action, and verification procedures.

Firms inspected all had written food safety plans but a number had issues with the plan noted on inspection. These included lack of proper implementation the plan (507.31a), no Preventative Control Qualified Individual (PCQI) or failure to document a change in PCQI (507.31b), food safety plan not specific to the facility (507.31c), and failure to include signatures (507.31d).

Hazard Analysis – 21 CFR 507.33

- A hazard analysis must be conducted to identify and evaluate known or reasonably foreseeable hazards for each type of feed manufactured.
- The hazard analysis must be written and consider potential to cause injury or illness to humans and animals.

Only one of our inspections noted a compliance issue with hazard analysis. The specific discussion item was a failure to identify all known or reasonably foreseeable hazards (507.33b). If a firm produces sheep feed, excessive copper should be considered in the hazard analysis. Regardless of the type of animal feed produced, we would highly recommend that firms consider mycotoxins as a biological hazard.

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

FERTILIZER PRODUCT REGISTRATION FOR 2023 IN KENTUCKY

All Kentucky fertilizer registrations and licenses expire on December 31, 2022 and must be renewed to legally sell fertilizer in the state for 2023. Renewal notices to all current Kentucky registrants/licensees will be mailed or emailed in early November. The renewals list all products registered in the state for 2022, all licenses approved for 2022, and instructions for completing the task.

BE ON THE LOOK-OUT FOR YOUR RENEWAL NOTICE

As always, if you have questions
Call: 859 257-2785,
Fax: 859 257-9478, or
E-Mail: June.Crawford@uky.edu

**Stephen McMurry,
Fertilizer and Seed Program Director**

SURVEY OF COMMERCIAL VALUES OF FERTILIZER NUTRIENTS

In early December you will receive a survey to determine the commercial values of fertilizer nutrients. Under the provisions of KRS 250.401, I am

conducting a survey to determine the commercial values of the fertilizer nutrients for Calendar Year 2023. This survey is of utmost importance for the Division as well as the retail community of fertilizer sales. The values will be published and used in determining and assessing penalty payments if needed. It is important that we include as many surveys as possible. Our inspection staff will be asking if you have received and/or responded to this survey. Please note that we want the current retail value of fertilizers in dollars per ton. All information will, of course, be held in strict confidence. You can give the survey to your respective inspector or fax to 859-257-9478 to the attention of Steve McMurry or e-mail to smcmurry@uky.edu.

**Stephen McMurry,
Fertilizer and Seed Program Director**

Emergency Planning and Community Right-to-Know Act

The Environmental Protection Agency (EPA) contacted us with a request to reach out to our stakeholders to ensure that everyone complies with the chemical inventory reporting requirements of the Emergency Planning and Community Right-To-Know Act (EPCRA).

EPCRA was created to help communities plan for chemical emergencies. It requires industry to report on the storage, use, and releases of certain chemicals to federal, state, tribal, territorial, and/or local governments. It then requires these reports to be used to prepare for and protect communities from potential risks.

EPA has developed a fact sheet [EPCRA Reporting Requirements for Fertilizer Retailers](#) to help fertilizer retailers comply with EPCRA reporting requirements. Please click on this link as the fact sheet explains the retail fertilizer exemption under EPCRA section 311(e)(5) and provides an overview of all EPCRA reporting requirements. Contact our office if additional information is needed and we will try to assist.

**Stephen McMurry,
Fertilizer and Seed Program Director**

Tornado Recovery Update for the Princeton Soils Lab

Nearly a year ago on Dec 11 a devastating tornado destroyed the UK Research and Education Center in Princeton which housed the soil testing laboratory in western Kentucky that we manage. All samples in the state have since been handled in the laboratory in Lexington. There has been progress in restoring all functions in Princeton in addition to the soil test laboratory. Temporary office and lab trailers are being installed for work to continue until the Center is rebuilt. One of two office trailers is currently housing personnel. A trailer for soil laboratory is being planned for temporary service until the Center is rebuilt. Activity in the trailer lab will be at about 80% capacity of the soils lab before the tornado. Soils will be received, ground, and prepared for analysis. Soil pH will be determined with an updated robotic pH instrument. Soil nutrients will be extracted from the soil and the soil extract solutions will be transported to Lexington for analysis. Plant tissue nutrient and soil organic matter were new tests introduced in the Princeton before the tornado occurred. These new tests will not be performed in the temporary trailer labs but will be reintroduced when the Center is rebuilt.

It is difficult to predict dates for when activities will resume in Princeton. There are several processes needing to be completed for meeting insurance requirements and contractors are in high demand in the area that experienced such devastation. Rough dates for soils lab to be active in the temporary trailer lab is late spring 2023. The soils lab is hoped to be active in the rebuilt station in 2025.

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

Inspector Update

New Inspector: I would like to welcome Daryl Derosssett from Glasgow to the inspection staff. His territory is the following 11 counties: Barren, Edmonson, Grayson, Green, Hardin, Hart, Larue, Meade, Metcalfe, Monroe, and Nelson.

2022 New Crop Corn Samples: Each fall the inspectors sample new crop corn across the state to get

a determination of how protein content of corn is testing. We also run mycotoxins on each of the new corn samples to determine if there are any issues with the new corn crop.

To date we have sampled 48 corn samples and the average protein content for 2022 has been 6.9% protein. This is a little higher than the previous couple of year's protein levels. However, there is still a wide range from the highest protein, 8.4% to the lowest protein, 5.4% protein. When formulating your feed rations for this next year, it is important to know protein level for the corn you are using at your mill. With the cost of soybean meal and other ingredients in feed rations it can vary greatly in the cost of your feed you are manufacturing. If your inspector has not sampled your 2022 new crop corn, let them know and they can take a sample on their next visit to assist you in formulation of your feeds for this winter.

There have been no samples tested this year with any measurable aflatoxin present. There have been some samples showing some presence of fumonisin in this year's crop. If you have new crop corn you want tested for mycotoxins please have your inspector collect a sample for the lab to test for you. Don't forget that if your feed mill is large enough for a Preventive Control inspection, that mycotoxins are a hazard that needs to be controlled in your food safety plan.

FDA Feed Mill Inspections: 2022 is an even number year which means you are required to renew your registration for all feed mills for the bioterrorism act. The inspection staff will be conducting FDA inspections at 32 Kentucky feed mills over the next several months. We will be conducting inspections at 3 licensed medicated feed mills, 13 non-licensed feed mills, 2 feed mills that carry prohibited material requiring a BSE inspection and 14 firms that do not make medicated feed.

The Division of Regulatory Services has experienced well trained inspectors to assist you with any questions you may have about seed, feed, and fertilizer. Continue to stay safe and have a wonderful holiday season.

*Jim True,
Inspector Program Coordinator*

Personnel News –New Employees



Kristin Stierman started working at Regulatory Services on August 1, 2022 as a Laboratory Technician. Kristin has an Associate of Science degree from Rock Valley College in Rockford, IL and graduated *Summa cum laude* from UK this spring with a degree in Natural Resources and Environmental Science. She did a lot of laboratory work during her undergraduate studies and will be involved in both the milk and feed laboratories in our Division. She replaces Debie Dahn who retired in June.



Daryl Derossett started as an Inspector in our central territory on October 3, 2022. Daryl has a B. S. degree in Animal Science from Morehead State University. He has spent several years working in the feed industry and was most recently Assistant Feed Mill Manager at Burkmann Feeds in Glasgow. Daryl and his family live in Glasgow where they are actively involved in the purebred cattle business. His territory includes the following counties: Barren, Edmonson, Grayson, Green, Hardin, Hart, Larue, Meade, Metcalfe, Monroe, and Nelson.



Shuting Li started working with us on October 24, 2022 as a Research Analyst Senior. She has a B.S. degree in Applied Chemistry from Hebei Normal University in China and an M.S. degree in Food Science from Shenyang University in China. Shuting spent the last 16 years as a Laboratory Technician Senior in the Animal Science Department here at UK. She will be involved in the analysis of drugs, amino acids, and mycotoxins in feed samples for our Division. She replaces Rajna Tosheva-Tounova who retired in June.

Upcoming Events

Kentucky AgriBusiness Summit

November 8-10, 2022
Holiday Inn Hurstbourne
Louisville, KY

Kentucky Farm Bureau 103rd Annual Meeting

November 30-December 3, 2022
Galt House Hotel
Louisville, KY

Association of American Feed Control Officials (AAFCO) Midyear Meeting

January 17-19, 2022
Hyatt Regency San Antonio Riverwalk
San Antonio, TX

Association of American Plant Food Control Officials (AAPFCO) Winter Meeting

February 13-14, 2022
La Fonda On the Plaza Hotel
Santa Fe, NM



We at Regulatory Services hope each of you have a Happy Thanksgiving, Merry Christmas and Happy New Year.

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