Regulatory Services News

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Director's Digest

Significant Proposed and Enacted Legislation

The Innovative FEED Act of 2023

Legislation was introduced in the U.S. Senate on June 8 that could affect how some feed additives are approved. The Innovative Feed Enhancement and Economic Development (FEED) Act of 2023 (S. 1842) would amend the Federal Food, Drug and Cosmetic Act (FD&C Act) and establish a regulatory pathway for a new category of novel feed additives, called Zootechnical Animal Feed Substances (ZAFS). This is a bipartisan bill and would allow a new category of animal food additives to be regulated as food additives instead of as new animal drugs by the Food and Drug Administration (FDA).

Interest in this legislation stems largely from additives being researched that will reduce methane emissions in livestock. Such additives are already used in Europe and South America but have not been approved for use in the United States. The Innovative FEED Act would establish a pathway at FDA for a new category of animal food substances that act in the animal's gut microbiomes or the feed they are digesting to provide non-nutritive benefits. The goal is to speed up how quickly these products can reach the market. There are strict guardrails included in the bill that will ensure that only safe-to-use products would be eligible for this new additive category.

One of the sponsors of this bill is Senator Roger Marshall of Kansas. "My producers at home continue to want to make more with less and leave the world safer, cleaner, and healthier than they found it," Sen. Marshall says. "Since the feed industry doesn't have a pathway to bring certain feed products to market, innovation that could be happening here is instead happening with our competitors abroad."

This bill has broad support from the feed industry. Representatives from the National Grain and Feed Association, the American Feed Industry Association, the National Milk Producers Federation, and National Council of Farmer Cooperatives all released statements supporting the bill.

The Association of American Feed Control Officials (AAFCO) is also supportive of the Innovative FEED Act. "This proposal provides a pathway for

Director's Digest continued on page 3

What's Inside

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products that have the opportunity to greatly impact the feed industry, and still provides the appropriate level of oversight to ensure safety and consumer confidence," stated Austin Therrell, executive director of AAFCO.

Great Britain passes the Genetic Technology (Precision Breeding) Act 2023

Genetically Modified Organisms (GMO's) are still a hot topic with many consumers. The Precision Breeding Act was passed in Great Britain in March of this year and excludes "precision breeding" from being considered a GMO. Precision breeding covers plants and animals developed using modern biotechnology, such as gene editing, but where the genetic changes could have occurred through traditional breeding methods. This is different from genetic modification, where genes derived from an unrelated species can be introduced into an organism's genome to confer characteristics that could not naturally be found in that plant or animal. Precision breeding basically speeds up the processes that could occur through multiple generations of selective breeding.

Crops can be edited to enhance their flavor, nutritional content, and resistance to stresses such as disease or drought. Some potential benefits to precision breeding include (but are not limited to):

- Tomatoes fortified with Vitamin D – research shows up to 1 billion people worldwide suffer from a deficiency of Vitamin D.
- Reduction in pesticide usage – introducing resistance genes to seed crops can prevent yield losses to pathogens and insect pests.
- Wheat without asparagine (to prevent the formation of acrylamide) – acrylamide has been linked to increased risks of cancer and occurs naturally in foods containing the amino acid asparagine.

Using gene editing techniques in animals also shows promise.

- Using gene editing technology, pigs have been bred that have a resistance to porcine reproductive and respiratory syndrome (PRRS) which is a viral disease that causes extremely high morbidity and mortality.
- There is promising research that poultry with genetic resistance to avian flu could be developed.
- Reducing disease morbidity and mortality through precision breeding has the potential to not only improve food security but to maintain fewer animals and thus reduce land use, while at the same time reducing drug and chemical usage. These improvements could help with antimicrobial resistance and environmental pollution.
- Reducing disease morbidity and mortality would also reduce greenhouse gas emissions plus there is the potential to breed animals that inherently produce less methane.

Currently, there are no crops or animals resulting from precision breeding technology for sale as food in the United Kingdom, but gene editing techniques have produced products for sale elsewhere in the world including Canada, China, the US, Australia, and Brazil. With the new law, regulation of precision bred plants will come first. Additional regulations will need to be made by the Department for Environment, Food, and Rural Affairs before precision breeding can be used in animals.

In my opinion, both of these laws are significant in making our industry more sustainable and efficient. Both of these are important in producing food responsibly.

Darrell D. Johnson,
Executive Director

AAPFCO Terms and Definitions

Within the Regulations of the Kentucky Fertilizer Law, we reference the Association of American Plant Food Control Officials (AAPFCO) fertilizer terms, and definitions for nutrient sources. AAPFCO has two meetings a year in which membership votes to accept new terms and definitions for plant nutrient sources as either tentative or official. In order to become a new term or definition, the applicant submits their term along with lab analysis and efficacy data to support the term or definition. The following list are the terms and definitions being voted on during this year's Summer Meeting:

Calcium citrate and its hydrate forms, is the calcium salt of citric acid. Anhydrous calcium citrate has the formula $Ca_3 (C_6H_5O_7)_2$.
Motion to official:

Orthosilicic acid (OSA) is the monomeric form of silicon with the chemical formula $Si (OH)_4$ that is absorbed and transported in plants and is detected by the molybdenum blue heteropoly method.
Motion to official

Potato Extract - Is the liquid resulting from the physical pressing of potatoes. Before processing, the potatoes are washed with water, rasped, and mechanically separated into starch, fibers, and liquid extract. The potato extract is separated by filtration and the resulting liquid is concentrated. It is a source of nitrogen, available phosphorus and soluble potash.
Motion to tentative

Plant Extract - Is a substance resulting from the processing (physical or otherwise) of plant tissue. After concentrating, the resulting substance is a source of plant nutrients and/organic compounds. The definition is used by prefixing a term with the name of the plant(s) which the extract is derived.
Motion to tentative

Beneficial Plant Nutrient - Elements, other than those defined as primary nutrient, secondary nutrient or micronutrients, that are known for plant growth and development or for the quality attributes of the plant product, of a given plant species, grown in its natural or cultivated environment.
Motion to tentative

Stephen McMurry,
Fertilizer and Seed Program Director

Understanding Feed Sample Reports

The statute authorizing our inspectors to collect feed samples at Kentucky distributors (KRS 250.581) also requires our division to send the results of official samples to "*the person named on the label and to the purchaser*". Our policy is to send a copy of the report to both the guarantor and the distributor of the product. Additionally, the final purchaser or end user of the product, if known, will also receive a copy of the report.

We receive questions on interpreting the results listed on the report on a regular basis, especially from individuals or firms that have no history with these reports. I've included two examples of sample reports for illustration purposes. (pgs 6 & 7)

The lab sample number is located at the top and in the center of the report. This is the number that we will need if questions arise. Date sampled, date reported, inspector number, and sample status are located in the boxes on the second line. Status will usually be "Official" (collected under official methods) but you may also see a status of "Service"

for service samples. The manufacturer (guarantor) will be located on the left side of the page and the dealer (distributor) on the right. If the plant actually manufacturing the product is known, the name and address will be located below the dealer information. In addition to the name of the product on the label, the sample report also includes product form, package type, lot size, product number, and production code.

The Feed Master 12% Horse Pellet has two violative analytes – excessive acid detergent fiber (ADF) and deficient copper (Cu). Fiber guarantees will always have a maximum and no minimum except in the case of rabbit feed where both are required. On this equine label, copper has a minimum but no maximum. Calcium and salt have both a minimum and maximum guarantee. All label guarantees are recorded by the inspector but there may be analytes not tested and therefore not included (vitamins D or E, lysine, methionine). If crude protein, crude fat, or one of the fiber measures includes "NIR", then the value on the report was estimated using near infrared reflectance spectroscopy. If the guarantee minimum is "T" or "none", the values provided are for informational purposes. With some reports, you may notice the Report Comment at the bottom of the page contains additional information. In this example, a label review was requested due to a salt guarantee that did not conform to our regulations.

The Hillgrazers 14 Cattle Ration R20 Med product is an example of a product with a major violation withdrawn from distribution based on the sample results. In this case, the product did not meet the label guarantee for a medication, monensin. We declare violations as major if the health of animals or humans could be impacted by the violation. In 2022, about 10% of all violative samples had a major violation.

The determinations of passing, deficient, or excessive are based on the 2018 Table of Kentucky Analytical Variation (12 KAR 2:021). When a product sampled fails to meet any of the label guarantees, the manufacturer or guarantor – not the dealer or distributor - is asked to investigate and report back to the Feed Director. This includes products with major violations where the withdrawal from distribution was issued. Under KRS 250:581, the guarantor has the right to ask for a portion of the sample tested within 30 days of receiving a sample report.

While the request for investigation that accompanies lab reports with label violations is just a request, I would encourage all guarantors to fill out the form and make the needed corrections to the formula, the label, or both. With new follow up procedures in place, we are receiving responses from guarantors on greater than 60% of violative samples.

Dr. Alan Harrison,
Director Feed & Milk Programs

PCQI Training Meeting Planned for Fall 2023

The Feed Program of the University of Kentucky Division of Regulatory Services is in the planning process for a Preventative Controls Qualified Individual (PCQI) training course to be held this fall. An experienced instructor from the American Feed Industry Association will lead the training. Successful completion of this course will allow the individual to meet the requirements to be a PCQI under the Preventative Controls for Animal Food rule, understand the hazard analysis process, and learn the concepts needed to build a food safety plan.

The in-person course will be held in Bowling Green (location to be determined). The planned schedule for the course is three days with a Tuesday 1:00 pm start and ending at noon on Thursday.

You may have already received the survey to measure the interest in this meeting and available dates in September and October. If you would like to be added to the mailing list for information on this training, please contact ukfeed@uky.edu. The results of this survey will help us determine if we need to host another training in the future.

Dr. Alan Harrison,
Director Feed & Milk Programs

University of Kentucky
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College of Agriculture, Food and Environment

103 REGULATORY SERVICES BUILDING
LEXINGTON, KENTUCKY 40506-0275
Telephone (859)257-2785 - Fax (859)257-9478

MANUFACTURER 000A1C | LAB SAMPLE #: FD-23-04243 | DEALER 000MCM

SAMPLED: 6/27/2023 | REPORTED: 7/24/2023 | INSPECTION #: FD-23-JXK185 | STATUS: Official

Big H Feed Store
PO Box 1234
Cabin, KY 41567

Feed Masters
567 Beautifulview Lane
Nowhere, KY 40372

Product Name:	Form:	Where Sampled:
Feed Masters 12% Horse Pellet	Pellet	Dealer
Product #: DFTBA	Package:	Lot Size (tons):
Production Code: 8675309	Bag	1

Determination	Unit	GuarMin	GuarMax	Found	Comment
Crude Protein (Min)	%	12		12.2	passed
Crude Fat NIR (Min)	%	8		7.9	passed
Crude Fiber NIR (Max)	%		10	11.9	passed
AD Fiber (Max)	%		12	15.9	EXCESSIVE
ND Fiber NIR (Max)	%		32	36	passed
Calcium (Min/Max)	%	1	1.5	1.494	passed
Phosphorus (Min)	%	0.5		0.805	passed
Salt (Min/Max)	%	0.4	1.4	0.995	passed
Copper (Min)	ppm	40		23	DEFICIENT
Selenium (Min)	ppm	0.3		<1	passed
Zinc (Min)	ppm	140		117	passed
Sodium	%	none		0.391	
Potassium	%	none		0.854	
Magnesium	%	none		0.324	
Cobalt	ppm	none		<0.70	
Iron	ppm	none		190	
Manganese	ppm	none		170	

Report Comment:
Review label - Salt

The above described feed was analyzed by our laboratory under the Kentucky Feed Law and Regulations. Questions concerning this report should be sent to: G. Alan Harrison, Feed and Milk Program Director: alan.harrison@uky.edu

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Withdrawal From Distribution

103 REGULATORY SERVICES BUILDING
LEXINGTON, KENTUCKY 40506-0275
Telephone (859)257-2785 - Fax (859)257-9478

DEALER 000YSK

MANUFACTURER 000IMO | LAB SAMPLE #: FD-23-04086 | PLANT 000IMO

SAMPLED: 6/12/2023 | REPORTED: 7/24/2023 | INSPECTION #: FD-23-JXK137 | STATUS: Official

4 J's Feed
PO Box 4321
Sliceo Heaven, KY 40372

Quality First Feed & Grain
112233 Fairview Avenue
Duncan, KY 491290

4 J's Feed
PO Box 4321
Sliceo Heaven, KY 40372

Product Name: Hillgrazers 14 Cattle Ration R20 Med.

Form: Textured | Where Sampled: Dealer

Product #: 3.14
Production Code: load sheet 2hvy

Package: Bag | Lot Size (tons): 2

Determination	Unit	GuarMin	GuarMax	Found	Comment
Crude Protein NIR (Min)	%	14		14.1	passed
Crude Fat (Min)	%	3		2.8	passed
Crude Fiber NIR (Max)	%		18	18	passed
AD Fiber NIR (Max)	%		T	21.7	
ND Fiber NIR (Max)	%		T	45.3	
Calcium (Min/Max)	%	1.3	1.8	2.09	passed
Phosphorus (Min)	%	0.4		0.693	passed
Salt (Min/Max)	%	0.1	0.6	0.392	passed
Potassium (Min)	%	0.6		1.08	passed
Monensin	g/T	20		10.52	DEFICIENT
Sodium	%	none		0.406	
Magnesium	%	none		0.302	
Copper	ppm	none		7.92	
Cobalt	ppm	none		2.42	
Iron	ppm	none		271	
Manganese	ppm	none		48.3	
Zinc	ppm	none		129	

The above described feed was analyzed by our laboratory under the Kentucky Feed Law and Regulations. Questions concerning this report should be sent to: G. Alan Harrison, Feed and Milk Program Director: alan.harrison@uky.edu

Selling Deer Minerals in Kentucky

Deer season is almost upon us! This time of year, the Division of Regulatory Services (Division) routinely receives calls from Kentucky citizens wanting to start their own deer mineral or deer feed business. In this article, I hope to simplify the registration process for these new business owners.

All commercial animal feeds (this includes deer minerals and other deer feeds) must be registered with the Division prior to sale in the state of Kentucky. To register, a firm must submit a registration packet which includes:

A completed application form. This form can be found on our website at: https://www.rs.uky.edu/regulatory/feed/registration.php

- **A copy of each product label**. This can be an actual label or a legible copy.
- **Payment**. Submit $50.00 for each product sold *exclusively* in 10 pound packages or less *OR* for products sold in package weights above 10 pounds submit no payment at this time as a quarterly tonnage form will be provided to your firm.

Once the complete packet has been received by the Division, the label will be reviewed for compliance with Kentucky Feed Law and Regulations available at: http://www.rs.uky.edu/regulatory/feed/feed_laws/. We strongly encourage new Kentucky companies to submit a copy of all labels for review prior to printing as there are often changes required upon review.

We have also published pamphlets outlining the requirements of deer mineral and feed labels which can be found here: https://www.rs.uky.edu/regulatory/feed/feed_labels/. These pamphlets explain the basic required elements and formatting for deer mineral and feed labels.

If you are looking for assistance with the guaranteed analysis section of your label, we have a feed tag guarantee estimator in excel available online on the left hand side of our feed page: https://www.rs.uky.edu/regulatory/feed/. You can input your formulation into this excel file and it will estimate the guarantees that you will need to include on your labeling. Alternatively, for Kentucky based firms, our Division generally offers a complimentary laboratory analysis of a product for your firm once a year. If interested in this service, please contact ukfeed@uky.edu.

After the Division has completed a label review, you will be notified by mail or email if your registration has been accepted. If there are changes or additional information required, the Division will provide your firm with guidance about what must be done or provided to bring your labels into compliance.

Since regulation of deer products is handled on a state by state basis, a successful product registration in Kentucky ONLY allows you to sell your product in Kentucky. If you wish to sell your product(s) in another state, you must comply with that state's laws and regulations.

Once your firm has completed the registration process and all products are accepted for registration, you may sell those products in Kentucky. Please note that for small package products (those sold exclusively in 10 pound packages or less) annual renewal is required. Our registration year runs on a fiscal year basis from July 1 to June 30th. The Division will automatically send your firm a renewal application with renewal instructions in June for the upcoming fiscal year.

Still have questions? Please contact me at Kristen.mary.green@uky.edu.

Kristen Green,
Registration Specialist

Moving Forward with Improvements in Quality

As we look to the future I think it's safe to say that everyone wants to improve as they get older. This may cover anything from something as difficult as not procrastinating to something simple as completing one task a day, such as making your bed. In regards to quality in our laboratories, I think a goal for us to have is to not only improve ourselves in what and how complete a task, but to have longer termed goals such as how can we improve in a certain area. As the Director of Quality, I am looking forward in how we can improve our internal audits.

Auditing is defined as the on-site verification

activity, such as inspection or examination, of a process or quality system, to ensure compliance to requirements. An audit can apply to an entire organization or might be specific to a function, process, or production step. Some audits have special administrative purposes, such as auditing documents, risk, or performance, or following up on completed corrective actions.

There are different types of audits, depending on the purpose of it. Some audits are named according to their purpose or scope. An audit may also be classified as internal or external, depending on the interrelationships among participants. Internal audits are performed by employees of your organization. External audits are performed by an outside agent. Internal audits are often referred to as first-party audits, while external audits can be either second-party or third-party.

There are a number of on-line and in-person trainings for ways to improve your own auditing program. All of them are training from the ISO/IEC Standard 19011:2018B which is the International Standard, "Guidelines for auditing management systems". But not all are necessarily geared to our specific needs. As a way of reaching our goal is to understand this standard and take the portions most applicable to what we do to improve our own auditing plans.

This standard was updated in 2018 to align it more with the terminology contained in the new management system standards that have a common structure, identical core requirements, common terms, and core definitions. The main way this standard has been updated to consider a broader approach to management system auditing, to provide guidance that is more generic, and to be more flexible. Although this standard can provide input to the analysis of aspect of business planning, we will be using it to help identify improvement needs and activities. In addition to giving guidance on the management of an audit program, on the planning and conducting of management systems, it gives guidance on the necessary skills and the evaluation of an auditor or audit team.

There are seven main principles of auditing that will help an organization improve its performance. One is integrity, which is a founding principle of professionalism. Auditors should perform their work ethically and undertake audit activities that they have been sufficiently trained and are considered competent. Auditors should perform their work in an impartial manner so they remain fair and unbiased in all of their audit activities. And he or she should be sensitive to any influences that may affect their judgement during these.

The second main principle of auditing is "fair presentation", which means to report findings truthfully and accurately. Any obstacles that are considered significant during the audit and any differing of opinions while performing an audit between the auditor(s) and auditee should be included in the final report. Auditors should also ensure the report is truthful, accurate, objective, truthful, clear, and complete to ensure that the difference of opinion or obstacle is fairly representing both parties.

Due professional care should be used by the auditor to show diligence and judgement in the auditing process. Auditors should be careful in accordance of the task they perform and stay true to the confidence placed with all information they get during the process. Another reason auditors should show due professional care is having the ability to make reasoned judgements in all audit situations.

A very important factor not just in audits, but in our own professional lives is confidentiality. The audit client and other interested parties should be treated with professionalism by not using information from the audit for personal gain by any of the involved parties. Confidentiality also means handling sensitive or confidential information properly.

Independence is the basis for the impartiality of the audit and objectivity of the audit conclusions. Auditors should be independent of the activity being audited where practicable. Auditors should be free from bias and conflict of interest. This means in internal audits, the analyst that uses a method to analyze a sample for a certain analyte should not perform the audit on their method. That doesn't mean that they do not participate! The analyst is considered to be an expert on that method and should be able to show you where records are located and

(continued on page 10)

answer questions about the method for clarification purposes.

Audit conclusions in the final report should be solely based on evidence obtained during the audit. The audit process should be a logical, purposeful, structured approach to decision making. It is not an unplanned, haphazard process. This allows the audit process to reach reproducible and reliable conclusions. All evidence should be able to be verified. The evidence should be based on examples of real records or samples of the information that is available.

Finally, the audit process should be a risk-based approach. During the process risks and opportunities should be reviewed. This approach should influence the planning, conducting, and reporting of audits to make sure that the audits are focused on items that are significant for the client and to achieve the audit program objectives.

These are only the tip of the iceberg to conduct a productive audit. We will discuss more ideas as to how to improve our audits and other items in our quality toolbox.

We currently have 19 chemical and microbiological methods and 47 analytes on our scope of accreditation. We will be adding more as we continue to improve. Our Scope of Accreditation and our Certificate may be found at the following link: Touchstone:Accreditation & Assessment Management System - Customer Portal (a2la.org)

We are continually evaluating our operations, policies, and standard operating procedures so that we provide unbiased quality results for our customers. We are continually looking for ways to improve our quality standards. We will continue to improve so that our consumers, stakeholders, and farmers are protected.

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

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