Regulatory Services News

Feed-Fertilizer-Milk-Seed-Seed Testing-Soil Testing

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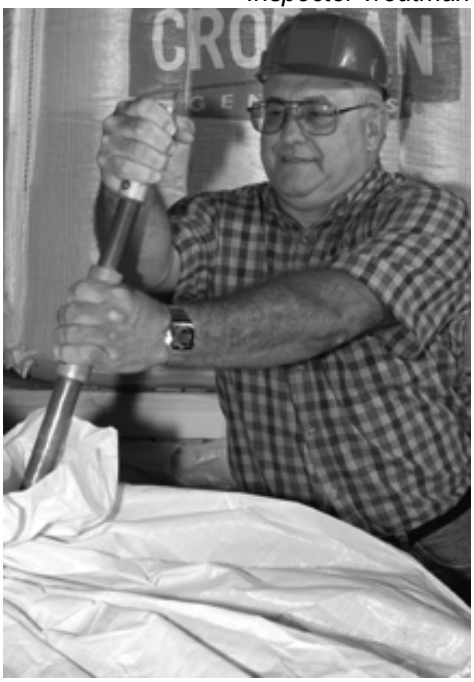
Inspector David Troutman Retires

David Troutman retired November 4 from his position as Regulatory Specialist. His career as an inspector in the Green River area of Kentucky began in January of 1978. David has been responsible for a multi-county territory with major production of corn, soybeans and livestock. In this territory, David has served the fertilizer, feed and seed industry and provided consumer protection for agricultural producers.

Inspector Troutman



While much of his work involved sampling products for testing, David devoted considerable time to working with fertilizer blenders, feed manufacturers and seed processors to assist with adoption of appropriate processing and manufacturing procedures that resulted in products that met guarantees and requirements of the law. Additionally, David provided area residents with consumer protection for specialty seed and fertilizer for lawns and gardens and pet food. David

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Troutman Retirement,
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was quick to provide service to the integrated poultry operations by sampling and assuring the quality of incoming ingredients.

David grew up on a family farm located in McLean County with agricultural emphasis on dairy, tobacco and corn. David has continued to reside on the family farm and maintain a beef cattle operation. Prior to joining the Division, David began a ten-year teaching career at Sacramento High School then at McLean County High School when the schools consolidated in 1972. During his teaching career, David taught math and chemistry and served two terms as President of McLean County Education Association. He also coached basketball and remains an avid sports fan.

David obtained a BS degree from Kentucky Wesleyan College in Owensboro and an MS degree from Western Kentucky University at Bowling Green. His area of study was chemistry.

We extend appreciation to David for his contributions to the Division and his service to the businesses and consumers in the Green River area. Congratulations and best wishes to David, Wilma and the Troutman family.

Eli Miller, Director

Division Personnel Update

Recent changes to Division personnel include two new employees in the feed and fertilizer laboratory and one new office staff employee.

Melissa Wayland has joined the lab as a Research Analyst. She will be working in the feed drug and mycotoxin analysis areas. Melissa came to work for Regulatory Services in October with previous lab experience in environmental, pharmaceutical and chemical manufacturing analytical support. **Gary Coleman** has joined the laboratory as a Senior Laboratory Technician in the sample receiving and preparation area. Gary came to work for Regulatory Services in October. He has experience in medical, water treatment, and environment labs. Both Melissa and Gary will be very valuable in our efforts to provide excellent analytical support and to continue to expand our lab capabilities.

Carol Filbin began as the Division's new accounts clerk in September. Carol is a native of Pikeville, KY, but has lived in Lexington for many years. Her experience in the banking industry will benefit the Division's programs as she performs data entry and completes accounting tasks for the service and regulatory programs.

C. Finneseth, Editor
M. Bryant, Feed/Fertilizer Laboratory

2004 Inspector Training Seminar
Nashville, TN

The majority of our inspection staff was able to attend the Volunteer Inspector Training Seminar held in late September. David Buckingham represented AASCO and gave a presentation on seed inspections and sampling techniques. Inspection techniques were also discussed in the areas of feed and fertilizer. Other topics discussed included time management, demographics in agriculture, dealing with conflict, investigative techniques and report writing. Feed and fertilizer practical application training was conducted at Tennessee Farmer's Cooperative in LaVergne, TN. These training seminars are essential in promoting uniform labeling and sampling of feed, fertilizer, and seed for consumer and industry protection.

S. McMurry, Inspection Program

Invasive Plant Legislation

During the previous legislative session in Kentucky, a bill to create a pest plant board was introduced. The purpose of this board, to be created within the Natural Resource and Environmental Protection Cabinet, was to protect the Commonwealth's land and waters from the negative impacts of invasive weeds. The bill, titled HB 127, considered before the Agriculture and Small Business Committee this spring, did pass out of committee but was not considered as the legislative session ran out of time.

Efforts to define and create a listing of invasive plants began at the federal level several years ago with an executive order signed by President Clinton. Work has been extensive and a reference to plant species suggested as being invasive can be reviewed at the website http://www.denix.osd.mil/denix/Public/ESPrograms/Conservation/Invasive/appendices.html. This list consists of many plant species harmful to the environment and agriculture. A review of this invasive plant list also reveals many valuable agricultural plant species including clovers, corn, crownvetch, rice, sorghum, soybeans, tall fescue, tobacco and wheat.

Within our state, The Kentucky Exotic Pest Plant Council has an Invasive Exotic Plant List, which can be reviewed at http://www.se-eppc.org/states/KY/Kylists.html. The list does include plant species that have been and are currently used in agricultural applications across Kentucky, including crown vetch, KY 31 tall fescue, sericea lespedeza, white sweetclover, yellow sweetclover, Korean lespedeza, Kentucky bluegrass, annual (Italian) ryegrass, alsike clover, red clover and white dutch clover.

HB127 as originally filed would have replaced the noxious weed listing in the regulations under the Kentucky Seed Law. The terminology in the bill equated invasive plants to noxious weeds. Use of this terminology has also occurred on the national level and has created confusion. State seed laws and the Federal Seed Act have noxious weed lists and their presence is either restricted to a rate of occurrence per pound or they are prohibited from being present. This apparent confusion exists because groups compiling invasive plant listings are not aware of state or federal seed control laws that regulate movement and commerce of seed. Groups compiling these lists focus on preservation of existing remnant native plant areas, re-establishment of native plant populations, preservation of woodlands and wetlands, and providing wildlife habitat.

The effect of legislation incorporating invasive plant lists into state law and regulation has been negative in some northeastern states. Agricultural species placed on these lists have been prohibited in state- and federally-funded seeding projects because these species have been *legislatively* declared as invasive. Similar actions in this state could have serious effects on the seed trade and agriculture. Kentucky currently has approximately 5 million acres of pasture/ hay. This acreage consists primarily of a tall fescue-legume base. These fields support our livestock industry and are a primary source of hay and summer and winter grazing. Crown vetch has long been used to cover steep banks and re-establish cover after road construction. Lespedezas, especially sericea lespedeza, have been used extensively to re-establish cover in mine reclamation areas.

Efforts to preserve remnants of native areas and re-establish native plant populations should not be in conflict with the needs and requirements of modern production agriculture. Preservation and agriculture have coexisted and complimented one another for years. One of the major purposes of re-establishing native plant species has been to provide wildlife habitat. Wildlife populations in Kentucky are thriving and probably larger than prior to the advent of modern agriculture. Private landowners are largely responsible for

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FDA PUBLISHES FINAL RULES FOR LIQUID AND FREE-CHOICE MEDICATED FEED

The Food and Drug Administration (FDA) announced changes to the regulations for liquid medicated feed and free-choice medicated feed. The most significant change that will affect the Kentucky Feed Manufacturer was the registration requirement. Prior to this change, most manufacturers mixing medicated liquid feed and free-choice minerals were required to be registered with FDA prior to manufacturing. The new regulation states that "for both the liquid and free-choice medicated feed final rules, FDA concluded that an approved medicated feed mill license is required for facilities that manufacture feeds using category II drug(s) or manufacture those products using category I drug(s) that must follow proprietary formulas or specifications. This means that certain liquid and free-choice medicated feeds will no longer require an approved medicated feed mill license for their manufacture."

The announcement included definitions relating to liquid and free-choice minerals. FDA defined liquid medicated feed as a physical form of animal feed that contains an approved new animal drug; other feeds may be dry. Free-choice medicated feed is a feeding system where medicated animal feed (dry or liquid) is offered to animals free-choice, that is, animals have access to the feed at any time and consume it at their will.

By changing the regulations for liquid medicated feed, FDA wants to clarify: what data are required to demonstrate chemical and physical stability of a drug in liquid feed, how such data may be submitted for use in the new animal drug approval process, and which liquid medicated feeds will require an approved medicated feed mill license. By changing the regulations for free-choice medicated feed, FDA wants to ensure that they are consistent with the requirements for liquid medicated feed, and that provisions for free-choice medicated feed and liquid medicated feed comply with the terms of the Animal Drug Availablitiy Act (ADAA) of 1996 (http://www.fda.gov/cvm/index/adaa/adaatoc.html).

The final rule was published in the May 27, 2004 (http://www.fda.gov/OHRMS/DOCKETS/98fr/04-11943.htm), *Federal Register*. Single copies of the final rule may be obtained by writing to the Communications Staff, FDA/Center for Veterinary Medicine, 7519 Standish Place, HFV-12, Rockville, MD 20855. Please send a self-addressed adhesive label to assist in processing your request.

The proposed rule was published in the May 28, 2003, *Federal Register*. The final rules for liquid medicated feed and free-choice medicated feeds adopt the proposed rules without change. The final rule will become effective June 28, 2004. Additional information is available in the May 27, 2004, *Federal Register* and from Dr. Dragan Momcilovic, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-0169, e-mail: dmomcilo@cvm.fda.gov.

S. Traylor, Feed Regulatory Program

Meeting Announcements

Association of American Feed Control Officials (AAFCO) - January 23-26, 2005, Memphis, TN

Association of American Plant Food Control Officials (AAPFCO) - February 19-24, 2005, Phoenix, AZ

Have you heard?

Mark your calendar for upcoming meetings of interest for Kentucky's dairy industry.

Southern Dairy Conference	The Westin Atlanta Airport Atlanta, GA	February 15-16, 2005
Kentucky Association of Milk, Food and Environmental Sanitarians (KAMFES)	Executive West Hotel Louisville, KY	February 22-24, 2005
Kentucky Dairy Conference	Cave City Convention Center Cave City, KY	March 1, 2005
National Conference on Interstate Milk Shipments (NCIMS)	Hyatt on Capitol Square Columbus, OH	May 12-17, 2005
Dairy Product Association of Kentucky (DPAK) Technical Conference	Hampton Inn Bardstown, KY	June 14-15, 2005

FDA Approves Rumensin® for Increased Milk Production Efficiency in Dairy Cows

On November 3, 2004, the U.S. Food and Drug Administration approved Rumensin® (monensin sodium) for increased milk production efficiency in dairy cows.

Rumensin®, a product of Elanco Animal Health, a division of Eli Lilly and Company, Greenfield, Indiana, is already approved in feed for therapeutic and production uses in feedlot cattle, pasture cattle (beef and dairy heifers, and slaughter, stocker feeder cattle), beef cows, and calves excluding veal calves.

Rumensin® is the first, approved new animal drug feed ingredient for dairy cows that increases milk-production efficiency. FDA reviewed extensive data to ensure the product met all necessary efficacy, animal health, human food safety, and environmental standards. FDA has concluded that the meat and milk derived from dairy animals fed monensin sodium are safe when the animals are fed according to the approved labeling.

Previous caution statements on the label will remain including the caution not to feed to horses or other equines as ingestion of monensin sodium by horses has been fatal.

FDA's approval of Rumensin® for use in feed for lactating dairy cattle constitutes a safe use of monensin sodium when used according to the approved label. As a feed additive, extra-label or off label use of monensin sodium is illegal and is not permitted under the Animal Medicinal Drug Use Clarification Act.

Mills that are planning on mixing monesin containing dairy rations will need to comply with the Good Manufacturing Practices (GMP). Part of the GMP regulation states that certain requirements will need to be met to be in compliance with equipment clean-out procedures, labeling, facilities and equipment, product quality assurance, and records and reports. If you have any questions or comments, please feel free to contact me.

S. Traylor, Feed Regulatory Program

A VISIT TO SOUTH AFRICA

Introduction

In August 2004 I was invited by IFDC, Muscle Shoals, AL to participate in a training session in Pretoria, South Africa. The purpose of the workshop was to explore the critical design and implementation elements in establishing agricultural input regulatory systems that protect the consumer and at the same time are compatible with open markets and the promotion of regional and international trade. The main focus of the training was the harmonization of fertilizer, seed, and pesticide laws among the countries of southern and western Africa. My topic was how the "Association" model promotes uniformity in the fertilizer, seed, and pesticide laws in the US. There were other presentations on the European and African models.

The king of beasts, Felis leo

I will use the model of the Association of American Plant Food Control Officials (AAPFCO) to illustrate how uniformity in fertilizer regulation in the US is achieved, although I also discussed how the Association of American Seed Control Officials and the Association of American Pesticide Control Officials promote uniformity of seed and pesticide regulation in the US, respectively.

Purpose of the AAPFCO

In summary, the purpose of the Association is to provide a forum through which officials of any state, territory, dominion, province, federal or other governmental entity on the North American Continent, Hawaii and Puerto Rico, and employees thereof, charged with a responsibility in the enforcement of laws regulating the production, storage, labeling, distribution, sale or use of fertilizers may unite to promote uniform and effective legislation, definitions, rulings and enforcement practices.

AAPFCO promotes uniformity in the regulation of fertilizers among its members through adoption of model legislation, regulations, definitions, and policies, all of which have been developed through a consensus process involving committees, task forces, investigators, and a Board of Directors. The bylaws of the Association state in very specific terms how a change to any of the "officially adopted documents" (OAD) may be accomplished which is done always in open forums.

Promotion of Uniformity

There is no federal fertilizer law.

AAPFCO's motto is: **"UNIFORMITY BY CONSENSUS"**. This means that all opinions and other inputs are sincerely solicited and considered when the Association develops a new OAD or when a part of one of the documents is amended. AAPFCO utilizes several mechanisms to promote its OAD.

The primary promotion tool is the encouragement of all control officials to participate in the organization by attending its annual and mid-year meetings and participating in the committee activities. Control Officials who attend the meetings and participate in the Association's Committee activities are more likely to become supporters of the Association's concept of uniformity and are more likely to use them when amending their individual state laws. This is critical.

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Drug Residue Monitoring in the Dairy Industry

Food safety is a number one priority in the dairy industry. One of the most important aspects of our industries' food safety program is its "Appendix N" or drug residue testing protocols. All milk is screened for the presence of drug residues prior to being processed. The screening test kits and procedures used by our modern dairy industry have undergone tremendous scrutiny prior to being approved for use. The following article provides information on this approval process. The article was published in the July/August 2004 issue of *FDA Veterinarian* and is reprinted with FDA's permission. If you need further information on drug test kits, testing procedures or the laboratory/analyst "certification" process for testing and screening milk for drug residues, you may contact one of Kentucky's Laboratory Evaluation Officers, Lucinda Mitchell or Matt Nelson, at the Division of Laboratory Services in Frankfort, KY (502) 564-4446.

FDA Validates Rapid Screening Tests for Antibiotics in Milk

by Philip James Kijak, Team Leader, Analytical Methods Team, Office of Research

This article is based on a presentation the author made at the 2004 Mid-Atlantic States Conference for Bovine Practitioners sponsored by the Maryland Veterinary Medical Association on March 25, 2004.

The ability of regulators in the United States to test every load of milk sold for the presence of antibiotics is a complex regulatory and technical achievement, supported by the Food and Drug Administration's (FDA) ability to test the milk screening test.

A national conference made up of State and Federal food regulators initiated the testing requirement in 1991. The regulators, along with representatives of the farmers, dairy industry and consumer groups, are organized as the National Conference on Interstate Milk Shipments (NCIMS). The purpose of the NCIMS is to develop regulations used by the States for Grade A milk and milk products in interstate commerce. The NCIMS developed the requirement that all tankers of milk in the United States be screened for residues of penicillin and other beta-lactam antibiotic drugs.

The only way to comply with that requirement, while at the same time not unduly delaying the delivery of milk, is through the use of highly accurate rapid screening tests. The United States had many commercial tests available, but did not have any program in place to determine whether these tests were suitable for use in a regulatory program. This is where FDA plays its role. NCIMS requested FDA to develop a program to validate these rapid screening tests for regulatory use.

FDA developed a validation program for test kits through a cooperative effort with the AOAC Research Institute. AOAC International, formerly known as the Association of Official Analytical Chemists, operates its Research Institute to provide independent certification on the performance of various commercial rapid screening tests. Under this program, FDA uses testing both by the kit manufacturer and an independent laboratory to determine the suitability of the kits for regulatory use.

In order to be considered for regulatory uses, a test kit must be able to detect—at or below the legal tolerance (safe level)—four of the six beta-lactam type antibiotic drugs commonly used in dairy cows. The six beta lactam drugs are ampicillin, amoxicillin, ceftiofur, cephapirin, cloxacillin and penicillin G.

In addition, all new tests must be capable of giving a printed record that includes the sample identification, date, time, operator, kit lot and result. When the program was first started, FDA would accept tests that required an operator to visually interpret the results and determine whether the milk was safe. Problems found with the use of the visually read tests led to the requirement in the late 1990s that all new test must be read by an instrument.

Sensitivity, selectivity

If a test can meet the preliminary requirements, then the primary focus of the validation is a test kit's sensitivity and selectivity.

Sensitivity relates to the possibility of false negatives and selectivity to the possibility of false positives.

Sensitivity is the ability to detect a specific beta-lactam drug in milk. To calculate a test kit's sensitivity, the independent laboratory tests a statistically significant number of samples of the test kit over a range of drug concentrations up to the tolerance level. The researchers are trying to determine the concentration of the drug at which the kit gives a positive result 90 percent of the time with 95 percent confidence (90/95). In other words, the test must be correct with 90 percent of the samples 95 percent of the time. The researchers run this test with each type of beta-lactam drug that the kit should be able to detect.

Selectivity is determined by the response of the kit to truly drug-free milk. To be acceptable, a kit must not give more than two positive readings for 60 known negative samples.

Researchers then do additional studies to be sure the test kits work properly when used in the field. One study is designed to determine the ruggedness of the kit. It evaluates the effect of slight changes to operating conditions, such as specified temperature, volumes and times, that would be expected under typical use of the test kit. Another study is designed to find out if the kits will give false positives or negatives when other veterinary drugs that might be used in dairy cows are in the milk. Additional studies test the performance of the kit when high levels of somatic cells or bacteria are present in the milk.

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What Impacts Milk Quality?

It seems like the importance of producing and marketing high quality milk is a never-ending discussion. Today's dairy retailers and consumers are quite demanding and successful processors are always looking for innovative way to meet these customer demands. These demands center on quality. Traits of a high quality dairy product include a consistent, fresh taste and a long shelf-life. The minimum standards set forth in the Pasteurized Milk Ordinance (PMO) does not always provide the level of quality needed to produce these high quality dairy products. In order to produce the type of dairy products that will meet these customer requirements, dairy processors are demanding higher quality supplies of raw farm milk.

Processors tightly monitor all aspects of milk quality. Table 1 compares some of the minimum PMO requirements with commonly observed processor quality requirements.

Table 1. Comparisons between regulatory requirements and typical processor milk quality standards.

Quality Parameter for Commingled Loads of Milk	PMO Requirement	Typical Processor Standard*
Milk Temperature	≤45°	≤42°
Standard Plate Count (SPC) Bacteria *(SPC limit for an individual producer is ≤100,000/ml)*	≤300,000/ml	≤100,000/ml
Preliminary Incubation Count (PIC) Bacteria	No requirement	≤100,000/ml
Antibiotic screening	No positive results	No positive results

*Some processors may have more stringent qualifying factors as well as additional quality requirements.

Marketers of raw farm milk have implemented quality incentive programs to encourage production of the highest quality milk to meet these tighter quality provisions. These incentive programs urge producers to examine every aspect of their operation so they can meet these quality standards and achieve quality pay premiums.

Of the tests identified in Table 1, the Preliminary Incubation Count (PIC) has recently generated the most discussion. Processors monitor PIC on their milk supplies to bolster their efforts to ensure that milk of the highest quality is entering their facilities. As a result, the use of the PIC has been implemented into several raw milk buyers' producer quality premium programs.

What does the PIC and other bacteriological tests mean?

The Standard Plate Count (SPC) of raw milk is an indication of the total number of aerobic bacteria present. These bacteria originate from a wide range of sources including the cow's udder, poorly prepped teats, dirty milking equipment and poor milk cooling. The SPC is conducted by "plating" the

fresh (less than 48 hours old) sample in a growing media and incubating it for 48 hours at 90° F (32° C).

The PIC is a test used to determine if poor hygiene practices are present on the farm and is most useful when compared with a SPC. To make a valid comparison, the PIC should be conducted on the same milk sample. The PIC is conducted by taking the portion of the milk sample to be tested (the portion remaining after the initial SPC test is begun) and incubating it at 55° F (12.8° C) for 18 hours and then performing another SPC test. The 18-hour incubation period "stresses" the sample, thus promoting certain types of bacteria growth. The source of the bacteria that thrive during this incubation period can typically be traced back to unclean milking equipment or poor milk cooling.

Table 2 provides a very basic outline relating to comparisons between the SPC and PIC.

Table 2. Comparison of standard plate count (SPC) and preliminary incubation count (PIC)

	SPC	PIC	Information obtained
Herd 1	10,000/ml	15,000/ml	Hygiene not a problem
Herd 2	10,000/ml	30,000/ml	Potentially inadequate cleaning or cooling
Herd 3	80,000/ml	90,000/ml	Further investigation needed to determine bacteria source

Briefly, here are a few basic items for producers to closely monitor to ensure good milk quality and desirable PICs.

Good udder and teat prep, milk clean cows.

Maintain a clean milking system from milking units to tank. Never put milk in a tank that has not been properly washed **and sanitized**.

Make sure the wash system is properly operating. This includes proper water heater temperature and accurate discharge of cleaners and sanitizers.

Ensure bulk tank cooling system is functioning properly. While milk can legally be stored at temperatures between 40° and 45° F, bacteria detected by the PIC can grow at these temperatures. A good rule is to get the milk cold fast and keep it cold, ideally around 36° F.

Make sure the tank agitator is functioning properly. Inadequately agitated milk will not stay uniformly cold.

Milk should be cooled quickly and stored at a recommended temperature of approximately 36° F.

Milk Quality, continued from previous page
Milk haulers can influence milk quality tests too!

Milk haulers frequently visit many different types of dairy facilities. Over time, they become experts at evaluating milk quality and they often develop trouble-shooting skills. Haulers should be able to readily recognize improperly operating tank equipment and should immediately inform producers when they observe malfunctioning tank agitators and poorly performing cooling systems.

Milk hauling equipment and procedures can also influence the PIC results for the entire tanker load of milk as well as for each individual producer. As stated earlier, the PIC test will quickly identify unclean equipment. This means the hauler should always start the day with a clean truck and equipment. Below are key items that should be closely monitored by milk haulers:

Ensure the truck tank has been washed and sanitized within the last 72 hours. Always check the truck's wash tag to ensure a properly cleaned and sanitized truck.

Ensure the stainless steel sample dipper is clean and stored in an appropriate strength sanitizing solution. The dipper well should be regularly broken down and thoroughly cleaned. Use test strips to verify the sanitizer strength.

Ensure the truck is properly washed and sanitized after unloading milk at the plant. Carefully breakdown and clean all hoses and gaskets when cleaning the pump and equipment.

Examine hoses, gaskets and fittings for air leaks. Unsanitary air entering the pumping system has potential for elevating bacterial counts.

Always start the day with a clean and sanitized pump and hose. It is not uncommon for some loads of milk to be picked up over a two-day period. Milk remaining in the pump and hose for extended periods provides the ideal conditions for bacterial growth. Make the effort to clean and sanitize this equipment when necessary.

The utilization of sanitary hauling procedures is equally as important. Conscientious haulers will always follow these standard procedures to ensure accurate bacteriological tests (as well as other tests) of milk:

Always use sanitary procedures, frequently wash hands.

Only use sterile, single-use sample containers. Never touch the inside of the container or lid and discard any dropped or damaged sample containers.

Do not touch the inside of the sample container

Obtain a proper sample and immediately place it in an ice and water mixture. The sample must be kept between 32° and 40° F. If the sample becomes warm, it is basically being incubated and bacteria will rapidly increase.

Rinse and sanitize the bulk tank outlet valve. All of the milk pumped from the farm tank will flow through this valve. If it is not cleaned and sanitized, the risk of detrimentally impacting the quality of the load is elevated.

Promptly place milk samples in the sample storage refrigerator after arriving at the receiving station. The PIC is very sensitive to both time and temperature. Therefore, the goal should be to get the sample to the testing laboratory as soon as possible. Promptly placing samples in the storage refrigerator puts them one step closer to the lab.

Milk samples should be stored in an ice and water solution and kept between 32° and 40° F.

Raw milk bacteria originate from a number of sources. Regardless of the origin, everyone involved in today's dairy industry has a vested interest in eliminating bacteria from any possible source. Properly used milk quality tests can be useful in determining the sources of bacteria and if accurately interpreted can assist producers in improving milk quality. However, these tests are only valid if the milk hauler uses clean, sanitary equipment and follows proper hauling procedures. If everyone does their part, high quality milk should be available to meet the demands of today's marketplace.

References:
Cornell University Department of Food Science. 1998. Sources of Microbial Contamination as Detected by Various Bacteriological Procedures. Available at: http://foodscience.cornell.edu/mqip/FACTbactest.doc

Cornell University, Department of Food Science. 2004. The Preliminary Incubation Count for Raw Milk. Available at: http://foodscience.cornell.edu/mqip/FACTpic.doc

C. Thompson, Milk Regulatory Program

Renewal of Seed Permits and Registrations

Applications for annual seed permits and registrations will be mailed in December. Required application(s) will be sent to each location as determined by the current permit/registration status for the location.

Any firm that labels agricultural seed, vegetable seed, flower seed or combination seed, mulch, fertilizer products is required to obtain a permit. Seed dealers that sell seed in container sizes of 40 pounds or more and locations that clean uncertified seed are required to register.

Please complete the application(s) you receive and return to our office promptly. The fee required for your application(s) will be written on the notice to renew. Please send only the amount that is indicated. Multiple applications, in most circumstances, require only a $25 fee. Thank you in advance for your prompt response. Questions about permits/registrations can be directed to the Seed Program at (859) 257-2785.

D. Buckingham, Seed Regulatory Program

PET & SPECIALTY PET FOOD SOLD FROM BULK RETAIL DISPLAY

The Kentucky Commercial Feed Law requires that all commercial feed be labeled for distribution. Two situations have prompted us to issue this advisory.

1. **Feed products removed from the manufacturer's original package and placed in a bulk display container for retail sale**

   The manufacturer has the initial responsibility for labeling and registration of the product. Once the product is removed from its original container then the dealer/ retailer has the responsibility for ensuring the product is properly labeled. Provided the dealer does not alter the product, then it is acceptable to label the display bin with the manufacturer's original product label. The law requires a label to accompany each sale. Our policy is that a label needs to be available for the purchaser of dog and cat treats and specialty pet foods, when desired. The manufacturer's label should always be provided for complete pet foods and products requiring special feeding instructions. A suggestion is to have additional labels or copies of the manufacturer's label available at the display or checkout counter.

Note: If the dealer prepackages the product for retail sale, then the dealer has responsibility for the product and must meet all requirements of the feed law including labeling the product, registration prior to offering for sale, payment of inspection fees and product quality. A $50 per product annual registration fee is required for products sold exclusively in a package weight of 10 pounds or less. Products sold in a package weight over 10 pounds or in bulk are subject to an inspection fee of 35 cents per ton or a $25 minimum inspection fee each calendar quarter.

2. **Products manufactured on site, such as gourmet baked treats for dogs, which are offered for sale in bulk quantities from a display counter**

   The manufacturer must label the displayed product with all required information. Registration is required prior to distribution. A $50 annual inspection fee is required for products sold exclusively in a package weight of 10 pounds or less. Products sold in bulk from the retail display (not prepackaged) are subject to an inspection fee of 35 cents per ton or $25 minimum inspection fee each calendar quarter.

Quantity Statement- A quantity statement of net weight or net contents is required for all products. For products that are sold from bulk, such as bird feed, the quantity statement is the actual weight of the sale (for example 4 lb). For small items that are sold individually as a bulk item, the net weight statement is not quite as obvious. For example, the sale of small bone shaped dog treats may be by the individual treat. In this situation, the quantity statement may consist of a count of the item or a net weight such as ounces.

The Kentucky Commercial Feed Law requires specific information be provided on the label.

1. Product Name
2. Guaranteed Analysis
3. List of Ingredients
4. Directions for Use
5. Manufacturer's Name and Address
6. Quantity Statement

continued on the following page

See the example label below for guidance. For related information please visit the "Feed Labels" link at our website. If you have any questions concerning registration and labeling please contact me at tburden@uky.edu or 859-257-2785.

T. Burden, Feed Registration

Little-Bitty

Kitty Snacks

Guaranteed Analysis

Crude Protein (min)……..14%
Crude Fat (min)……..……..4%
Crude Fiber (max)……..……..2%
***Moisture (max)…..……..10%**

Ingredients

Wheat Flour, Egg, Vegetable Oil, Natural and Artificial Flavors

Feeding Directions

Feed as a treat or reward.

Tracy's Pet Food Company
103 Regulatory Services Bldg.
Lexington, KY 40546-0275

Net Count ___ treats

** A moisture guarantee is not required for wild bird feed.*

Regulatory Services Hosts Ukrainian Farmer Delegation

Regulatory Services had the honor of hosting a delegation of Ukrainian farmers. This opportunity was presented by the Louisville International Cultural Center through its Community Connections (CC) program. CC is a professional development and cross-cultural program sponsored by the Department of State, Bureau of Educational and Cultural Affairs, Office of Citizen Exchanges. Their mission is to introduce participants to American business, local governance, legal practices and culture to encourage direct and lasting links between communities in the United States and Ukraine.

The Division presented a half-day program about activities in the regulatory and service programs. Eli Miller welcomed the delegation and provided a review of Regulatory Services. David Buckingham, Seed Program Coordinator, discussed Seed Regulation in Kentucky and the US. Chris Thompson, Milk Program Coordinator, reviewed milk regulation at the state and national level. Dr. Steve Traylor, Feed Program Coordinator, gave an overview of feed regulation in Kentucky and national issues. Dr. David Terry, Coordinator of the Fertilizer Program reviewed goals and activities of fertilizer regulation for Kentucky and nationally. Dr. Frank Sikora, Soil Testing Program Coordinator, provided a tour of the soil laboratory. Bob Kiser, Laboratory Supervisor, conducted a tour of the feed and fertilizer laboratory and reviewed testing activities. Cindy Finneseth, Seed Testing Coordinator, discussed seed testing activities, GMO crops and conducted a tour of the seed laboratory.

The Ukrainian delegation employed two language interpreters. The farmers had numerous questions and communications was easily accomplished. It was our privilege to host the delegation and participate in international cooperation.

E. Miller, Director

Feed and Fertilizer Analytical Laboratory Update

Field Efforts

A field visit was made to a manufacturing facility to review potash analysis. The visit resulted in plans to compare analytical results on some share samples. The visit was used to review the plant process, sampling protocol, sample preparation techniques and the final analytical determination performed on the material. The lab used more than one technique to determine if potash content is dependent on the analytical protocol. A flame photometric system, a titration technique, and a plasma emission system can be used for comparative purpose. Extraction of the sample, wet digest of the sample, and ashing followed by digestion can be used to test the material. This provides a rather extensive evaluation of materials in order for the potash content of a sample to be confirmed.

Workshop Attendance

James Bartos and Melton Bryant attended a Training Workshop arranged and presented by Alltech. Karl Dawson, Director of Worldwide Research, planned the content of the workshop. Methods for analysis of enzymes, mycotoxins, and selenium were discussed and lab demonstrations of these analyses were performed. These methods and application to feed material were reviewed. The workshop provided insights to these analytical determinations and we learned about a new instrument for very low level Se determinations. After the workshop, Alltech arranged for several of attendees to visit Regulatory Services. All the labs in our facility were toured: seed, soil, milk, fertilizer and feed.

Lab Collaboration

In another effort to maintain excellence in the laboratory, the Special Feed Lab was chosen by the Ankom Corporation to assist in a study for the crude fiber determination equipment used for this analysis. Approximately 15 labs in the U.S. were chosen to participate. This study is being undertaken to establish the Ankom fiber method for AOCS approval. Sample materials analyzed by our lab to date have resulted in good agreement with Ankom results. Debbie Sipe has been conducting the lab determinations with Anne Harper and Bob Kiser providing assistance.

Fertilizer Metals Presentation

Other long-term projects include a nationally coordinated effort to ensure the quality of fertilizer being used in Kentucky. Our lab has been monitoring “non-nutritive” metal content in various fertilizer materials for the past few years. James Bartos attended the American Chemical Society meetings on Aug 25th and 26th in Philadelphia PA, where this topic was discussed. James gave a presentation entitled “Digestion Comparison of Hotplate, Hotblock and Microwave Methods for Fertilizer Metals.” The data presented was from a collaborative study involving private and state labs from Kentucky, Florida, Indiana, North Carolina, Idaho and Texas. Attendees included individuals from the fertilizer manufacturing industry, private testing labs, regulatory labs, USDA, and the bioassement fields. Considerable interest exists regarding whether regulatory labs need to test and/or report non-nutritive metals content in fertilizer materials. UK is active in the discussion and methodology development regarding non-nutritive metals in fertilizer products. Comparison of the commonly used digestion techniques was seen as an important contribution for this important aspect of the materials. James also participated in the fertilizer metal digestion workshop held in conjunction with the meeting.

National Associations

Melton Bryant attended the AAPFCO and AAFCO meetings in Madison, WI. The lab is represented on the Slow Release Fertilizer Committee, the Magruder Check Sample Committee, Fertilizer Lab Services Committee, and the Feed Lab Services Committee. The Fertilizer Metals Forum also conducts sessions to plan future work at the next full meeting on measuring adulterant metals. The lab supports and provides input for these laboratory committees. Currently, methods are being prepared for collaborative studies in the feed and fertilizer areas.

M. Bryant, J. Bartos and R. Kiser
Feed, Fertilizer and Milk Laboratories

FDA Evaluates Test Kits to Detect Animal Proteins in Animal Feed

In a CVM Update, Scientists in FDA's Center for Veterinary Medicine announced the results obtained from two commercial test kits that designed to detect animal proteins in animal feed. Discovery of a Canadian-born cow with Bovine Spongiform Encephalopathy (BSE) in the State of Washington in December 2003 raised awareness of the need for increased screening of animal feed to ensure the absence of prohibited animal proteins in ruminant feed. Scientific evidence has demonstrated a clear link between the practice of feeding ruminants, such as cattle, the rendered remains of other ruminants with the spread and dissemination of BSE.

Because the FDA does not have pre-market approval over veterinary diagnostic devices such as feed test kits for detection of prohibited animal protein, the Office of Research in FDA's Center for Veterinary Medicine (CVM) initiated a study to evaluate the performance characteristics of several commercially available test kits. The study included two tests that used lateral flow, or "dip-stick" diagnostic devices designed for general use, and two that were designed for use by laboratory personnel. This CVM UPDATE presents the results of the FDA's completed evaluation of the two lateral flow test kits; Neogen Corporation's "Reveal for Ruminant in Feed" test and Strategic Diagnostics Inc.'s (SDI) Feedchek test.

CVM researchers found that Neogen's test was 100% selective when conducted by multiple analysts. Selectivity is the capacity to detect true negative samples. Therefore, this test never gave a false positive result. The test was able to detect animal protein down to only 1%, which was the level stated in the label guarantee.

CVM researchers evaluated Strategic Diagnostics Inc.'s test and observed variable selectivity that seemed to be related to difficulty in reading the test. Sensitivity is the capacity to detect true positive samples. The test exhibited 62% selectivity when conducted by one analyst and 97% selectivity when conducted by another analyst. Therefore, the test reported false positives in 3% and up to 38% of the samples. The test was able to detect animal protein to the level of 0.1%. False positive samples are true negative samples that were incorrectly identified as being positive.

FDA also identified critical issues with reading the results for both test kits. The color development begins when the test strips are placed in solutions extracted from the feed sample. Neogen's test strips were accurate only when they were read 15 minutes after color development had begun. SDI's test strips were accurate between 3 and 5 minutes after color development had begun. Reading the SDI test longer than 5 minutes after color development has been initiated can potentially result in false positive reactions, as test strips turn positive after 5 minutes. Therefore, when using these test kits, it is important to take the readings at the appropriate time intervals.

These critical pieces of information were not contained in the package inserts of the test kits FDA evaluated, and could potentially lead to incorrect interpretation of the test strips, resulting in a false negative determination if read too soon (both Neogen and SDI), or a false positive determination with the SDI strips if read after 5 minutes. The Neogen Corporation has already incorporated this change (reading the strip 15 minutes after initiation of color development) into their package insert. False negative samples are truly positive samples that were incorrectly identified as negative.

These test kits can be an important tool for surveillance and quality assurance although they appear to be less sensitive than feed microscopy and polymerase chain reaction (PCR) techniques that are capable of detecting at least 0.1% bovine meat and bone meal.

S. Traylor, Feed Regulatory Program

AAPFCO in South Africa, continued from page 6

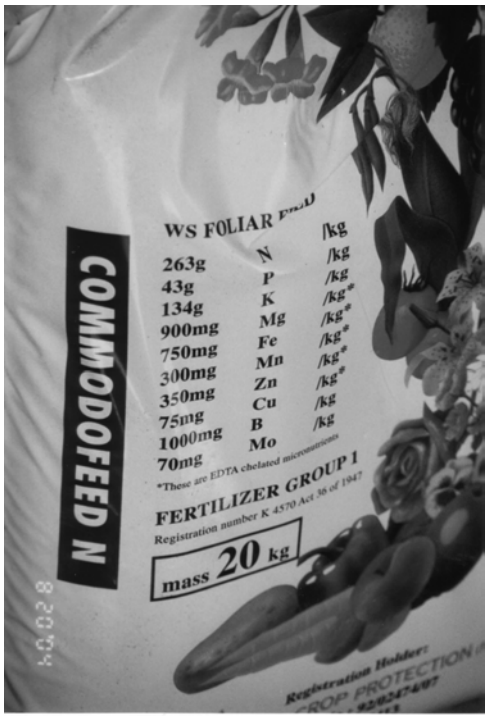
The next most important avenue used to promote the OAD (and maybe as important as the primary) is through the support of the fertilizer industry. This includes individual industry members; and, national, regional, and state industry organizations. By encouraging the participation of the industry in the Association's activities and allowing them valid input in the drafting of OAD, the industry is more likely to support their adoption at the state level. Most state legislatures are sensitive to the needs of the industry and in almost all cases their support is essential for amending the state fertilizer law. This cooperation is accomplished without collusion.

The other major stake-holder in adoption of uniformity is the consumer. This includes primarily farmers and "farm" organizations. Support of the farmers is critical to legislative adoption and is primarily achieved by working with farmer organizations and convincing them of the value of uniformity and standardization.

Dave and Gwen Terry compare pods of the legume soabean or sea heart, Entada gigas, which can grow up to 6ft in length

Training programs for fertilizer law administrators and inspectors are other important tools to promote uniformity. The AAPFCO Seminars Committee conducts annual "Fertilizer Administrator" seminars where Control Officials responsible for administrating state laws meet and discuss the AAPFCO OAD and how to achieve uniformity. The Committee also conducts periodic "Inspector" Seminars where the field inspectors from several states are brought in for intensive training on uniform inspection and sampling techniques. AOACI's official fertilizer sampling methods and tools are emphasized as recommended by AAPFCO.

AAPFCO also publishes brochures that promote various aspects of the organization and each year an an "Official Publication" is published and distributed having the latest OAD including any "tentative" items.



A fertilizer label for South Africa - quite different from labels in the US.

The Lesson

In the forum as organized by IFDC, I noted that all the participants were very serious in learning about harmonization and how that might be accomplished in their countries. Most of the countries do not have any fertilizer, seed, or pesticide laws so are just beginning to formulate them. The purpose of IFDC is to start the harmonization process before the laws are passed and to promote this idea to the government officials, the industry, and consumers within these countries.

We visited a seed and soil testing laboratory; and, a privately owned fertilizer, seed, and pesticide dealership. The laboratory was a modern operation in both equipment and methods. For seed testing they used the International Seed Testing Association methods and for soils they used the Bray-III extractant. The dealership was also modern in its storage and distribution

D. Terry, Fertilizer Regulatory Program

FDA Rapid Screening Test for Antibiotics, continued from page 7

Label

The kit manufacturer must include information that the researchers gather during the validation tests about sensitivity, selectivity, drug interference and other key findings in the instructions for use included with the kit, referred to as the kit label. This information makes the kit label the most important resource to the user when determining the appropriate kit to use.

The label includes both the calculated 90/95 concentration for each drug claimed and information on the response of the kit at specific drug concentrations. Both pieces of information are important in evaluating the sensitivity of a kit to a specific drug.

In the example in Figure 1, the concentration response curves to amoxicillin for two test kits are shown. The calculated 90/95 concentrations for the two kits are almost identical.

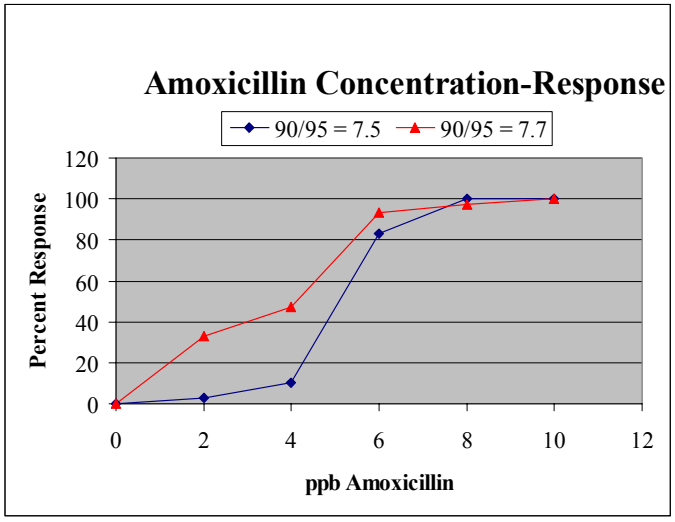
Yet, at low concentrations, the kit described by triangles gives a significantly greater percentage of positive samples.

The difference in sensitivity at low concentrations is documented in the label information. The respective sections of the label for each kit are shown in the second figure.

By reading and using the label information, the test kit users can make an informed decision about the suitability of a kit for their application. For example, if a milk producer wants to screen the bulk tank before pickup to ensure that it is not positive, the producer would want the most sensitive test possible.

Additional information required to be on the kit label includes a list of drugs known to cause either false positives or false negatives when present in the milk, information on the selectivity of the kit, and any other potential limitations to the performance of the kit that were discovered during the validation process.

Figure 1. Concentration response curves of two test kits to amoxicillin showing the difference in the kits' response.



Retest programs

The user of the test kit needs to be aware that the kits do have limitations.

Because the 90/95 concentration must be at or below the tolerance/safe level, the kits will always have the potential to give a false violative result, meaning that, although the drug is present and the kit indicated a violation, the concentrations is not at a level that would be in violation of the safety standards.

Figure 2. Examples of how the drug concentration response information shown in figure 1 is listed on the test kit label for both test kits.

Drug Concentration (ppb)	Amoxicillin	Drug Concentration (ppb)	Amoxicillin
		1	
1	3	2	33
3		3	
4	10	4	47
5		5	
6	83	6	93
8	100	8	97
10	100	10	100
14		14	
20		20	
Tolerance Safe Level (ppb)	10	Tolerance Safe Level (ppb)	10
90/95% Concentration (ppb)	7.5	90/95% Concentration (ppb)	7.7

To minimize the consequence to the milk producer from a test kit's false positive results, NCIMS calls for two retests of a sample before the milk is condemned. The initial retest is done using the same test as the one used for the initial screening. This retest is done in duplicate with the positive sample and a negative control sample. If either of the duplicate tests gives a positive result and the results for the positive and negative control are correct, the tanker load is a "presumptive positive." Then a second retest is done.

This second retest is also done in duplicate along with positive and negative control samples. The second retest sample must be tested in a State or State certified laboratory, and may be done using a different test kit. If either of the second retests is positive, the result is called a screening test positive, and the milk considered to be adulterated with beta-lactam residues.

The effect of the retest program is to greatly decrease the likehood of false positive results. For example, if a kit had a false positive rate of 1 in 1,000, the probability of a negative sample being positive for both the initial screen in the first retest is 1 in 500,000. If the same test is used for the second retest, the chances are only 1 in 250 million that true negative milk will be declared screening test positive.

The retesting also decreases the probability that milk with a beta-lactam drug present will test positive when the antibiotic's concentration is below the tolerance level. However, the effect is largely dependent on the concentration of the drug in the milk. At drug concentrations where the test kit usually gives a positive result, a negative retest is highly unlikely. But as drug concentration in the milk decreases to the point where the kit gives

continued on pg. 18

FDA Rapid Screening Test for Antibiotics, continued from page 17

negative results, the probability that the retest will give a negative result also increases.

No information about amount of drug

Even though modern kits present printouts that typically include numeric results, they often do not offer information about the amount of drug present. This printout does not actually give a good idea of the level of drug present, because of the test-to-test variability of most test kits.

Figure 3 shows some results obtained of a test kit's response to amoxicillin. The kit was functioning properly, and all negative results are well below the zero line. And at drug concentrations at tolerance and above, the result is always positive. However, there is a great range of actual readings obtained at any single concentration. For example, several of the high readings at 5 parts per billion (ppb) are well within the typical range of readings obtained at 12 ppb. If a user were to test milk with this test, and get a reading of 4 ppb, the drug concentration in the milk could be less than 5 ppb, greater than 12 ppb, or somewhere in between.

The sensitivity of the kit to each drug that the kit can detect for is different. This variability prevents the use of the test kit's numeric readout to determine the drug concentration in the milk.

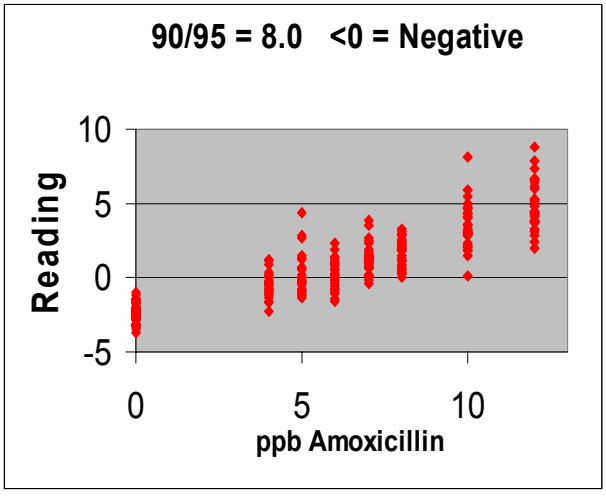
Limitations

The screening tests are meant to be fast and accurate. They are not meant to supply complete information about the potential of antibiotics in milk.

For instance, most kits will not test for all six beta-lactam drugs. And, in most cases, the tests do not provide information on what drug caused the positive result.

Still, the screening tests fulfill their principal duty—keeping the milk supply in the United States safe—while not slowing down delivery of fresh milk to consumers.

Figure 3. Results of test kit's response to amoxicillin showing why screening tests cannot be used to show drug concentration.



C. Thompson, Milk Regulatory Program

Invasive Species Legislation, continued from page 3

this population gain in wildlife species because landowners have supported the efforts of our fish/wildlife and natural resource/conservation professionals by providing cover and food for wildlife species. Most of these private landowners are involved in some phase of production agriculture that utilizes some of the plant species that have been placed on these invasive plant lists.

As HB127 was being discussed in committee this spring, changes were offered and included in the bill. These changes addressed the problem of replacing the Kentucky Seed Law's noxious weed listing with an invasive plant listing. Changes were made because of input of individuals involved in production and commerce of seed in Kentucky. An amendment to preclude the listing of agricultural crops on an invasive plant list was also promised. This amendment defined what would be considered as agricultural crops. The wording of the amendment read as follows; "This list shall not include agricultural crops. For purposes of this section, agricultural crops shall be those plant species that are used for production of food, feed, fiber, seed, grain, forages, turf, or for purposes of erosion control and land reclamation."

Future consideration of legislation to list invasive plant species will probably occur and agricultural plant species should be excluded from any such listing. All of us involved in the seed industry and production agriculture need to be involved in any process that would potentially limit responsible use of plant species valuable to our operations. We all benefit from activities of groups whose efforts are directed at elimination of harmful plant species that are truly a detriment to our environment and production agriculture; however, both groups - conservation and agriculture - need to work together for the benefit of everyone.

D. Buckingham, Seed Regulatory Program

2005 AAFCO OFFICIAL PUBLICATION

The Official Publication of the Association of American Feed Control Officials (AAFCO) is an essential reference manual for many individuals involved in the feed and pet food industry. This manual contains up-to-date information on the following:

- Model law and regulations for commercial feed, pet food, and ingredients.
- State, FDA and Canadian feed control contacts (address, e-mail, telephone, fax number).
- Approved feed ingredients and their definitions.
- Regulatory requirements for distributing feed products in each state.
- Medicated feed labeling guide.
- Analytical methods reference and analytical variations.
- AAFCO committees and industry advisors.
- Proceedings of the most recent AAFCO annual meeting.
- Canine and feline nutrient profiles and labeling guide.

The 2005 Official Publication is available to non-AAFCO members in the U.S. and Canada as well as international locations. Pricing and ordering information are available from:

Sharon Senesac, Asst. Secretary-Treasurer
P.O. Box 478
Oxford, IN 47971
Phone (765) 385-1029, Fax (765) 385-1032
E-mail: sharon@aafco.org

Visit the AAFCO web site www.aafco.org for the order form and other information.

S. Traylor, Feed Regulatory Program

Spanish Translation of the AAFCO Official Publication

The Association of American Feed Control Officials (AAFCO) recently announced that sections of the Official Publication are now available.

Questions about cost and ordering information should be addressed to:
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E-mail: sharon@aafco.org

S. Traylor, Feed Regulatory Program

Winter Break Announcement

The Division of Regulatory Services will be closed for winter break beginning on Monday, December 27. At 8:00 a.m. Monday, January 3, 2005, the Division will reopen.

The Seed Testing Laboratory will be open over the break. To arrange sample drop-off or to contact Seed Lab personnel, call (859) 257-2785, extensions 253, 254, 255 or 256. The seed program can also be reached by email at cfinnese@uky.edu.

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