Thoughts from the Director

Springtime always reminds me of lots of things. Some from the distance past of my childhood and some more recent. As a point of reference, I graduated from Breckinridge County High School before consolidation and the first state basketball championship in 1965. Some of the fondest memories are growing up on the family farm and living near a small town before Wal-Mart, Pizza Hut and a by-pass. The smell of freshly plowed ground, the burning of tobacco plant beds, using a cross-cut saw, arrival of baby chicks, new calves and all the activities associated with another crop year are recalled. Life’s pathway has taken me to the city but fortunately work in the College of Agriculture has kept me connected to farming and my work in Regulatory Services has allowed me to service agriculture for which I am very grateful.

The Division has responsibilities for regulation of feed, fertilizer and seed products, service testing of seed, assuring accurate testing of milk for payment purposes and the testing of soil samples for liming and fertilizer recommendations. Springtime always brings increased activity to the Division and our staff works increasing hard to provide timely inspection, testing and reporting to provide the service that are requested of us. The Division is continually trying to adapt our programs to the rapidly changing industries and individual services needed. We just recently completed a Strategic Plan for Regulatory Services that identifies ambitious goals and objectives for the next three years. This is an attempt on our part to stay progressive and continue to improve the Division’s service to the agricultural and urban community. You will be hearing more about the Strategic Plan in the future.

continued, pg. 2

What's inside....

Milk Program License Renewals ................................................................. 2
Seed Analyst Certification ........................................................................ 2
Animal Feed Safety System Update ......................................................... 3
Fertilizer Bulk Blend Workshops ............................................................ 4
Bulk Milk Storage and Sample Care ........................................................ 5
Annual Seed Inspection Report ............................................................... 6
KY Horse Treat Policy ............................................................................ 7
Selenium, Selenium Yeast Use in Feed .................................................. 8
Director’s Thoughts
continued from the front page
A web site is the new tool for presenting information and providing communications. Regulatory Services has had a web site for several years. Like many others we find it is a continuing challenge to keep the information current and in a format that is easily accessible and user friendly. The Division has a Web Site Committee that is attempting to keep us compliant with University and College guidelines and to make our web site informative and attractive for those that utilize it for information. To visit the site it can be found through the College of Agriculture web site (http://www.ca.uky.edu) or directly (http://www.rs.uky.edu).

The Division web site has useful information pertaining to the regulatory and service programs. This includes: laws and regulations; reporting forms; registration and license forms; publications; personnel; pricing & information for seed and soil testing; example feed labels; location map; inspection territories; and links to other state and federal agencies. We would encourage you to visit the UK, College and Division web sites.

E. Miller, Director

Milk Program License Renewals

Each year, licenses issued by Regulatory Services’ Milk Program expire on June 30. All handlers, laboratories, sampler-weighers, transfer stations and testers should receive a renewal notice and application by early June. Applications can also be obtained at the milk program web-site (www.rs.uky.edu). If you do not receive a renewal notice by June 15, 2005 and do not have access to the web-site, contact our office for an application at (859) 257-2785.

Seed Laboratory Analyst Receives AOSA Certification

Janice Zimmer became a Certified Germination Analyst in May. She was awarded the certification by the Association of Official Seed Analysts after completing a rigorous written exam and practical evaluation to demonstrate her abilities at the Iowa State University in Ames, Iowa. She will be formally recognized and presented with the certification at the association’s annual meeting in June.

Janice has been working for Regulatory Services for nearly four years and has been a seed analyst for nearly three years. She is originally from Warren, PA, but lived in Oldham Co., KY for many years. Janice has a B.S. degree in Natural Resource Conservation and Management from UK. She is responsible for planting and evaluation of the various seed kinds tested in the lab.

Every analyst in the Seed Lab is AOSA-certified. We have six AOSA Certified Germination Analysts and four Certified Purity Analysts.

C. Finneseth, Seed Testing Program

Janice Zimmer
The Center for Veterinary Medicine (CVM) that is developing the Animal Feed Safety System (AFSS) held a public meeting on April 5-6, in Omaha, NE. The focus of CVM’s second public meeting was to discuss the proposed draft framework that describes the features FDA believes should make up the feed safety system.

The draft framework, which covers all aspects of feed production, was published in February 2005 and it identified four components that will make up the feed safety system. The components explained below outline the purpose, goal and identified gaps within each component.

### Component 1: Ingredients and the Approval Process.
The purpose of this component of the feed safety system requires that all ingredients used in feed are safe. This component also describes the mechanisms FDA and CVM use to make sure all ingredients and additives used in feed are safe for the uses intended. The principal mechanism is the Federal Food, Drug, and Cosmetic Act. However, FDA has also relied on the Association of American Feed Control Officials to define ingredients. The gap identified under AFSS for this component is that a non-Federal organization is used to list ingredients and provide information. The framework document identifies the use of an FDA Compliance Policy Guide to correct the gap.

### Component 2: Limits for Animal Feed Contaminants.
The purpose of this component is to identify the hazards that feed might contain and set limits to those hazards. In addition, this component calls for developing test methods to find the hazards. One gap the AFSS team identified is the lack of a ranking process that would allow FDA to determine which hazards require limits and analytical methods. CVM is developing a risk assessment method, which was also discussed at the meeting.

### Component 3: Process Control for the Production of Safe Feed.
This component deals with proper manufacture, packaging, storage, and distribution of feed ingredients and mixed feed to keep hazards out. Current FDA regulations cover medicated feed manufacturers. However, under AFSS, FDA is exploring a broader regulatory approach to cover production, packaging, storage, distribution, and use of feed ingredients and non-medicated feeds.

### Component 4: Regulatory Oversight.
This part of the feed safety system calls for regulators to apply a risk-based system so that FDA can use resources for the greatest benefit in terms of keeping feed safe. One gap that the framework identified is that some segments of the feed industry, including transporters and on-farm mixers, are outside the normal regulatory scope of FDA and the States.

The public is welcome to make comments on the proposed framework document. Written comments should be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/dockets/ecomments.

S. Traylor, Feed Regulatory Program
Fertilizer Bulk Blend Workshops

The Division of Regulatory Services in cooperation with the Agri-Business Association of Kentucky, The Fertilizer Institute, and the Association of American Plant Food Control Officials will hold two bulk blend workshops in August. These will be latest in a long series of workshops dating back to about 1975.

Objective: To teach bulk fertilizer blenders the essentials of producing quality blends that are “on grade” and stay “on-grade” when bagged or handled as bulk.

When & Where: Tuesday, August 30, 2005       Wednesday, August 31, 2005
Lexington, KY       Hopkinsville, KY

The specific hotel at each location will be announced later.

What: This is the “tentative agenda”:
Each session will be: 8:30a.m.-4:00 p.m. local time

| 1. Plant Operations       | 4. Quality Control in Your Plant |
| - Good Housekeeping       | -How to do it                   |
| - Tips on Optimizing Operations | -Why it is important          |
| 2. Raw Material Selection | 5. Environmental Issues and Compliance |
| - What is available       | 6. Soil Testing                 |
| - How to get what you need| How, Why and How Come?         |
| 3. Formulations           | 7. Fertilizer Labeling - The Key |

Topics To Be Discussed

Who Should Attend?

All personnel involved in the blending operation including those responsible for:
(1) purchasing and handling the raw materials,
(2) calculating the formula for grades or custom mixes,
(3) writing the labels for bags, bulk blends, or custom mixes, and
(4) operating the equipment in the blend plant.

Mark Your Calendars Now!

Plan to Attend the Workshop Closest to Your Plant

Bring all personnel who have responsibilities within your plant for the blending operation.

D. Terry, Fertilizer Regulatory Program
Proper Bulk Milk Storage and Sample Care

Summer is almost upon us! As warmer temperatures approach, all of us who work in the dairy industry need to prepare for the extra demands that warm weather places upon us. As summer approaches, producers must address a wide array of concerns on the farm ranging from cow comfort to bulk milk storage. Many others involved in the dairy industry must also make summertime adjustments too.

Individuals who obtain or otherwise physically handle official milk samples are required to be licensed and should be well aware of proper sample handling techniques. However, the warm temperatures we encounter during the summer presents additional challenges in regard to milk sample care. Preparation for these warm-temperature challenges is essential to prevent problems. Let’s examine some of the most basic items and principles to focus on as summer approaches.

Cooling Milk on the Farm

Sanitary conditions and proper milk storage temperatures are essential for producer’s to properly store milk in a manner to obtain quality premiums. The ideal storage temperature for farm milk is around 34° to 36° F. Milk should be cooled to a temperature below 40° F within 30 minutes after completion of the first milking and the milk temperature should not rise above 45° F during any subsequent milkings. This means the bulk tank and cooling systems should be in “tip-top” shape during the summer. Condensers should be clean, free of oil and dust to ensure proper operation. Thorough but gentle milk agitation is also a necessity for proper cooling. We all realize that proper agitation ensures a homogenous blend of milk and enables haulers to obtain a representative milk sample. But good agitation also facilitates cooling because it eliminates “hot spots” and helps to prevent ice formation.

Haulers can assist producers by keeping them aware of their bulk tank’s performance. Haulers should closely monitor the bulk tank thermometer and at a minimum, compare it to a “certified” pocket thermometer monthly. These comparisons are required to be documented in writing. The producer’s barn card is usually considered the best place to record these comparisons. Producers should be alerted when temperatures vary from acceptable levels and when abnormalities such as ice build-up occur.

Sample Transportation

Each farm tank must be accurately sampled prior to the hauler picking up the producer’s milk. The sample will potentially be used for both component testing purposes for payment and other tests for milk quality. The most effective way to maintain the sample’s quality and to stabilize it’s microbial content is to store the sample between 32° and 40° F. Official samples should be immediately placed in a proper storage vessel. For haulers, this means using an insulated cooler, floaters or racks and an ample supply of ice and water. A short supply of ice and water can easily occur during the summer months. Haulers should frequently replenish ice supplies as needed to ensure samples are never exposed to warm storage conditions. In Kentucky, milk samples are frequently in transit for well over 12 hours while in the hauler’s sample cooler. This means ice supplies must be continually evaluated. We should all realize that keeping an ample supply of ice and water with milk samples is common sense, however, this important item is easily overlooked during hurried hauling activities.

continued on pg. 6
Receiving stations and labs are also required to provide proper storage for milk samples. Refrigerators used to store milk samples must be of sufficient size to prevent overcrowding. Overfilled refrigerators generally have problems with air circulation, which in turn results in poor cooling. Samples should be stored in as orderly a manner as practical. Ideally, units should be equipped with self-closing doors to ensure better cooling.

Refrigerators should maintain sample temperatures between 32° and 40° F. Obviously a storage condition exceeding 40° F must be addressed. An additional concern with refrigerator operation is the lower end of the appropriate temperature range. Samples should not be allowed to freeze while in the refrigerator. Thermostat adjustments should be made appropriately.

Detailed records are required for all milk sample storage refrigerators. *Standard Methods for the Examination of Dairy Products, 17th Edition* indicates, at minimum, an approved thermometer on both the top and bottom shelves be used to monitor each unit. Thermometers must be examined twice daily and documented with written records. When checking the refrigerator be sure samples are stored in an orderly manner. When necessary, clean and sanitize the refrigerator to maintain a sanitary condition.

Refrigerators in milk receiving areas must be in optimal working condition due to exposure to outdoor humidity and heat generated from trucks and other equipment. Perform routine maintenance prior to warm weather arriving. Have the unit’s compressor, freon level and door gaskets examined. Make sure individuals who access the refrigerator do not keep doors open for extended periods. Attention to seemingly minor details will go a long way towards ensuring proper sample storage temperatures.

**Other Sample Handling Issues**

Sample couriers and those who ship official samples also have a huge responsibility in regards to sample transportation. Couriers should carefully check each refrigerator’s temperature as samples are collected at each receiving station. Promptly notify a responsible person if the proper temperature range is not observed. Couriers as well as other individuals who ship samples are required to properly pack samples in insulated coolers. Pack samples in a manner to minimize leakers and ensure an adequate layer of ice between each layer of samples. Just as in the case with the milk hauler, extra ice is mandatory during the summer.

**Annual Seed Inspection Report**

The Annual Seed Inspection Report (2000-2004) is now available. This report summarizes regulatory inspection and laboratory activities over the past year as well as a five-year history. Printed copies have been mailed to all registered dealers or are available; contact David Buckingham at (859) 257-2785. The report is also available on the Division’s website (www.rs.uky.edu).
**Bulk Milk Storage and Sample Care**  
*continued from pg. 6*

### Why all the fuss over keeping milk cold?

Milk is a natural food of the young and is often described as being nature’s perfect food. It provides a wide variety of nutrients and is a vital component of a healthy diet. This near complete nutrition package also provides a highly suitable growth medium for microorganisms. These microbes grow rampantly at warm temperatures and cause milk and milk samples to deteriorate. If temperatures are warm for even brief periods, deterioration will occur. Be sure to do your part to assist producers in marketing high quality milk and take the necessary precautions to ensure a well maintained, representative milk sample is used for milk component and quality analysis. Be prepared in advance this summer, keep milk and milk samples cold!

*C. Thompson, Milk Regulatory Coordinator*

---

### Kentucky Policy on Horse Treats

Horse treats are unique products in multiple ways. Because horses are viewed as production animals by the Association of American Feed Control Officials (AAFCO), equine feed labeling should follow the Feed Regulations under the Model Bill. The Model Feed Regulations does not specifically address treat products for production animals. Only the Pet and Specialty Pet Food Regulations addresses treat products. The Commonwealth of Kentucky has established the following policy for labeling equine treat products:

If the product is represented solely as a treat, without any other claims associated with the product, we require a minimum crude protein percentage, minimum crude fat percentage, maximum crude fiber percentage, and a maximum moisture percentage be expressed in the guaranteed analysis.

Additional guarantees will be required to substantiate claims expressed on the label. For example, if a treat is represented to provide additional supplemental Vitamin E, copper and zinc then these nutrients will need to be included in the guaranteed analysis. In contrast, if the treat product is represented to be a vitamin and/or mineral supplement then the guarantees will need to follow the AAFCO guidelines as established in Table 1. Guarantees by Feed Type under the AAFCO Model Bill and Regulations (page 118, 2005 OP).

The policy was established because a typical treat is not intended to supply or be represented to serve as a principal source of supplemental nutrients especially when feed intake of the treat is considered on a total intake basis. Typically a treat product would not exceed more than 0.25 pounds of the animal’s total daily feed intake. A 1,200 pound horse should consume about 1.63% of their BW daily in dry matter. This equates into approximately, 19.5 pounds of dry matter daily. The treat product should be offered above and beyond the typical daily nutrient requirements.

*T. Burden, Feed Registration Specialist*
Selenium, long known for its toxic effects, only became recognized as an essential nutrient for livestock in 1957. The history of toxicity and question about selenium being a possible carcinogen brought into play the Delaney Clause which increased the difficulty in FDA clearance for selenium use in livestock feed. The initial approval came in 1973 after research demonstrated and FDA concluded that nutritional levels should not be classified as a carcinogen. This approval permitted the addition of sodium selenite and sodium selenate to complete feeds for growing chickens, swine and turkeys. Subsequent approvals followed for beef, dairy and sheep in 1978, laying chickens in 1979 and ducks in 1981. The latest revision occurred in June of 1987. Following the 1987 approval, environmental concerns were raised leading FDA in September 1993 to publish a final rule to amend the 1987 regulations. This action if implemented would have substantially lowered the approved rates of selenium supplementation. On October 13, 1994, Congress enacted Public Law 103-354 which effectively blocked FDA from implementing or enforcing this final rule and, thus, the higher supplementation rates were presented.

Selenium yeast approval
From 2000 to the present, several applications for use of selenium yeast were reviewed by FDA. Current regulations allow for use of selenium yeast in complete feeds for chickens, turkeys, swine, beef cattle and dairy cattle. Subsequently FDA has reviewed the use of selenium yeast in other animal diets. These reviews lead FDA to issue a letter stating that they will exercise enforcement discretion on selenium use in horse, sheep and goat diets. These decisions apply to any firm that manufactures and markets selenium yeast within the specifications of FDA’s Food Additive Regulation.

Frequently, we are asked about the approved uses of selenium and selenium yeast. The three approved sources of supplemental selenium are sodium selenite, sodium selenate, and selenium yeast. In an attempt to set forth the requirements, the following explanation is provided:

The applicable sections from the Code of Federal Regulations Title 21 573.920 (6) (b) through (h) provide the currently acceptable level of selenium supplementation administered in feed. This section reads as follows:

(b) The food additive selenium is a nutrient administered in animal feed as sodium selenite or sodium selenate or in a controlled-release sodium selenite bolus, as provided in paragraph (f) of this section.

(c) It is added to feed as follows:
   (1) In complete feed for chickens, swine, turkeys, sheep, cattle, and ducks at a level not to exceed 0.3 part per million.
   (2) In feed supplements for limit feeding as follows:
      (i) Sheep: At a level not to exceed an intake of 0.7 milligram per head per day.
      (ii) Beef cattle: At a level not to exceed an intake of 3 milligrams per head per day.
   (3) In salt-mineral mixture for free-choice feeding as follows:
      (i) Sheep: Up to 90 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 0.7 milligram per head per day.
      (ii) Beef cattle: Up to 120 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 3 milligrams per head per day.

(d) The additive shall be incorporated into feed as follows:
   (1) It shall be incorporated into each ton of complete feed by adding no less than pound of a premix containing no more than 272.4 milligrams (600 ppm) of added selenium per pound.
   (2) It shall be incorporated into each ton of salt-mineral mixture for sheep or beef cattle from a premix containing no more than 4.5 grams of added selenium per pound (9.9 g/kg).

(e) The premix manufacturer shall follow good manufacturing practices in the production of selenium premixes. Inventory, production, and distribution records must provide a complete and accurate history of product production. Production

continued on pg. 9
controls must assure products to be what they are purported and labeled. Production controls shall include analysis sufficient to adequately monitor quality.

(f) The label or labeling of any selenium premix shall bear adequate directions and cautions for use including this statement: “Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted.”

(h) The additive selenium yeast is added to complete feed for chickens, turkeys, swine, beef cattle and dairy cattle at a level not to exceed 0.3 part per million.

(1) Selenium yeast is a dried, nonviable yeast (Saccharomyces cerevisiae) cultivated in a fed-batch fermentation which provides incremental amounts of cane molasses and selenium salts in a manner which minimizes the detrimental effects of selenium salts on the growth rate of the yeast and allows for optimal incorporation of inorganic selenium into cellular organic material. Residual inorganic selenium is eliminated in a rigorous washing process and must not exceed 2 percent of the total selenium content in the final selenium yeast product.

(2) Guaranteed organic selenium content from selenium yeast must be declared on the selenium yeast product label.

(3) Usage of this additive must conform to the requirements of paragraphs (d)(1), (e), and (f) of this section.

General Consideration for Manufacturers Distributing Feed Containing Selenium and Selenium Yeast in Kentucky

The label for all commercial feeds must provide adequate directions for use to ensure that selenium supplementation does not exceed permitted levels.

Swine and Poultry
The complete feed for swine and poultry may be supplemented up to 0.3 ppm selenium from sodium selenite, sodium selenate, or selenium yeast. Protein supplements, base mixes, mineral and vitamin mixes and other products must have adequate directions for the purchaser to follow so that approved selenium use is achieved. Feed manufacturers also must ensure that feed products mixed at different rates to make complete feeds for different production phases such as swine starter or finisher provide adequate supplementation to meet the nutrient requirements for that production phase. The Kentucky labeling regulations requires a selenium guarantee for swine feeds but not poultry.

Beef Cattle
The complete feed for beef cattle can be supplemented up to 0.3 ppm of selenium from sodium selenite, sodium selenate, or selenium yeast in the total ration dry matter. The complete feed approval is generally applicable to cattle in the feedlot. Most Kentucky cattle are on pasture or fed stored roughage (hay/silage) and are not fed a complete ration. In this situation, beef cattle may be fed supplemental selenium, either free-choice or limit fed, at a level not to exceed an intake of 3 milligrams per head per day. This may be achieved by limit feeding of grain concentrates, protein supplements and free-choice salt-mineral mixtures. The highest recommended feeding rate for a product will establish the maximum selenium level in the product. The following are examples of product intake necessary to provide 3 milligrams of supplemental selenium at different selenium levels:

<table>
<thead>
<tr>
<th>Selenium Level</th>
<th>Intake to Provide 3 Mgs.</th>
<th>Example of Product Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3 ppm</td>
<td>22 lbs.</td>
<td>Grain Mix (limit fed)</td>
</tr>
<tr>
<td>0.6 ppm</td>
<td>11 lbs.</td>
<td>Grain Mix (limit fed)</td>
</tr>
<tr>
<td>1.0 ppm</td>
<td>6.6 lbs.</td>
<td>Grain Mix (limit fed)</td>
</tr>
<tr>
<td>1.5 ppm</td>
<td>4.4 lbs.</td>
<td>Grain Mix (limit fed)</td>
</tr>
<tr>
<td>2.0 ppm</td>
<td>3.3 lbs.</td>
<td>Grain or Protein Supplement (limit fed)</td>
</tr>
<tr>
<td>6.6 ppm</td>
<td>1.0 lbs.</td>
<td>Protein Supplement (limit fed)</td>
</tr>
<tr>
<td>17.6 ppm</td>
<td>6 ounces</td>
<td>Free-choice or Mixing Mineral</td>
</tr>
<tr>
<td>26.4 ppm</td>
<td>4 ounces</td>
<td>Free-choice or Mixing Mineral</td>
</tr>
<tr>
<td>35.2 ppm</td>
<td>3 ounces</td>
<td>Free-choice or Mixing Mineral</td>
</tr>
</tbody>
</table>

1Selenium yeast is not approved for free-choice feeding.

continued on pg. 10

Regulatory Services News, Second Quarter 2005 -- 9
Selenium and Selenium Yeast Use in Feed

continued from pg. 9

Selenium, when added, is a required guarantee on the label of beef mineral feeds, but not complete beef feeds and supplements. Manufacturers are encouraged to consider a selenium guarantee for all beef feeds to advise the purchaser of the level supplemented. This office encourages manufacturers to indicate in the feeding directions that “this product when fed at the recommended feeding rate of x (ounces or pounds) provides the maximum permitted selenium supplementation of 3 mg/head/day.”

Dairy Cattle

The selenium approval for dairy cattle is based on 0.3 ppm in the total ration dry matter intake from sodium selenite, sodium selenate, or selenium yeast. Lactating dairy cows may consume 45 pounds of dry matter. If this dry matter contains 0.3 ppm, then selenium supplementation of 6 milligrams/head/day is provided. In some instances, higher dry matter intakes may be achieved for very high producing herds but the 45 pound level appears to be a reasonable maximum unless otherwise justified. As a rule of thumb, the grain concentrate will generally be fed up to 50% of the dry matter intake with forages constituting the other 50%. Based on this, a typical commercial dairy concentrate may guarantee up to 0.6 ppm supplemental selenium without any special labeling or feeding directions. Provided, the selenium level is above 0.6 ppm, then specific directions must be provided on the label to advise the dairyman how to feed in order to achieve the approved level of 0.3 ppm in the total ration. Protein concentrates, supplements and mineral products that are mixed or limited fed must have appropriate directions to provide for approved selenium use. Products that are mixed should be labeled with appropriate directions to achieve no more than 0.6 ppm selenium in the typical dairy concentrate or directions to achieve 0.3 ppm in the total ration dry matter.

Note: A grain concentrate that contains 0.6 ppm selenium and is fed at the rate of 20 pounds/head/day provides 5.4 milligrams of supplemental selenium/cow/day.

For non-lactating dairy cows, a dry cow concentrate contains higher selenium levels may be warranted due to lower feeding rates. Specific labeling and directions for use are required to advise the dairyman of the intended use of dry cow concentrates. Selenium supplementation should be based on the 0.3 ppm approval. Supplementation approaching 6 milligrams of selenium/head/day to the non-lactating dairy cow does not appear justifiable.

Dairy Mineral

Free-choice feeding of a mineral that contains selenium is not approved in the selenium regulations. Minerals for lactating dairy cows are required to provide mixing directions and no free-choice indication is permitted. It is recognized that non-lactating dairy cows may receive little or no grain during the dry period. The only practical means of providing supplemental minerals to non-lactating dairy cows may be with a free-choice mineral. Therefore, labeling for dairy minerals may include free-choice directions for non-lactating dairy cows in addition to mixing directions for lactating dairy cows. The label should clearly caution not to feed free-choice to lactating dairy cows and use as the sole source of selenium to dry cows.

Sheep and Goats

The selenium approval for sheep is 0.3 ppm in the complete feed from sodium selenite, sodium selenate, or selenium yeast. The level in grain concentrates and supplements can be appropriately adjusted for

continued on pg. 11
forage dry matter in a manner similar to beef. In feed supplements that are limit fed, selenium supple-
mentation cannot exceed 0.7 milligrams/head/day. It is important to note that selenium yeast is not
approved for limit feeding and/or free-choice supplementation in sheep or goats and any use is subject
to FDA regulatory discretion. Free-choice feeding of a salt-mineral mixture to sheep at a rate not to
exceed an intake of 0.7 milligrams/head/day form sodium selenite or selenate is approved.

**Horses and Other Non-Food Producing Animals**
Selenium supplementation for horses and other non-food producing animals is not formally approved,
however, FDA has not objected to the supplementation of selenium from sodium selenite, sodium sel-
enate, or selenium yeast. Selenium supplementation that does not exceed 0.3 ppm in the total ration
seems compatible with approvals for food producing animals. Directions for use on the label of horse
feeds should provide for selenium supplementation rates compatible with 0.3 ppm in the total diet.

**A Word of Caution**
Selenium is a required nutrient, but also is extremely toxic. In some species, selenium levels no greater
than five times the requirement will produce toxicity. Proper formulation, manufacturing of feed products,
and providing accurate labeling to ensure the purchaser can properly use the feed product is essential.
This becomes increasingly difficult for feeds that do not constitute the total diet and when multiple feed
sources may provide supplemental selenium. The feed manufacturer must consider not only the supple-
mentation needs to the animal but traditional feeding practices that may alter the amount that can be
appropriately provided in a product. Special precautionary labeling may be necessary to advise the
purchaser to feed as the sole source of selenium. Specific labeling is required for selenium premixes.

**Label Review**
The Kentucky Commercial Feed Law requires all products be registered prior to sale or distribution in
the Commonwealth of Kentucky. Part of the registration process requires a product label be submitted
for review. The feed program reviews approximately 10,000 product labels annually. During the review
process the feed program closely monitors product labels for approved selenium sources as well as
approved use. This office frequently encounters free-choice mineral product labels that are false, mis-
leading and/or misbranded. The most common error found on feed labeling with respect to selenium is
the unapproved use level in free choice mineral products intended for ruminant animals.

The policy being implemented by this office will generally require the manufacturer to substantiate the
feeding level on free-choice mineral supplements containing selenium intended for ruminant animals if
the feeding directions are less than three (3) ounces per head per day for cattle and one-half (1/2) ounce
daily for sheep and goats. The rationale for this is that we have observed a trend for product labels to
understate the feeding level of free-choice mineral supplements for ruminant animals such that the
supplemental selenium level provided to the animal is above that approved by FDA. This policy is
intended to ensure that free-choice mineral products are safe and effective for their intended use and to
provide consumer protection to Kentucky livestock producers.

The preceding explanation is intended to increase understanding of the approved uses of selenium
sources in livestock feeds. It should also assist the feed industry in providing appropriate labeling for its
products and to facilitate adequate selenium supplementation for Kentucky livestock.

*S. Traylor, Feed Regulatory Program*

---

*Regulatory Services News, Second Quarter 2005 -- 11*
Regulatory Services News is published quarterly for the feed, fertilizer, milk and seed regulatory programs and the seed and soil service testing programs of the Division of Regulatory Services. It is provided free to persons interested in these programs. For subscriptions or address changes, contact Cindy Finneseth either by email at cfinnese@uky.edu or by telephone at (859) 257-2785. You can also access Regulatory Services News on the internet at http://www.rs.uky.edu.

Editor: Cindy Finneseth.

The College of Agriculture is an Equal Opportunity Organization