

# Regulatory Services News

Feed – Fertilizer – Milk – Seed – Seed Testing – Soil Testing

First Quarter 2003



Lewis "Ed" Hill (left) receives the Poundstone Award from Dr. Frank Sikora, Coordinator of the UK Soil Testing Laboratories

## Lewis "Ed" Hill receives 2002 University of Kentucky Poundstone Award

Lewis "Ed" Hill, Senior Technician at the University of Kentucky Soil Testing Lab in Princeton was the 2002 recipient of the Poundstone Award. The University of Kentucky Poundstone Award was created to annually honor an outstanding Regulatory Services' staff employee. Bruce Poundstone was Director of Regulatory Services from 1946 to 1971. He was nationally renowned for his leadership and innovations in the agricultural

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## **Poundstone Award continued from front page**

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in his honor.

Ed has worked at the UK Soil Testing Lab in Princeton for 20 years. He began his career at UK when the Soil Testing Laboratory opened at Princeton in 1982. He came to the soils lab with almost sixteen years of laboratory experience. He completed over 130 credit hours in college achieving an Associates Degree in science with emphasis in chemistry. Ed is a perfectionist when it comes to mixing standards, extracts and other chemical solutions and safety is always of utmost importance. He also carries this attitude of perfectionism to the testing of soils and maintenance of the lab equipment.

Ed is also known around the Research

*Frank Sikora -- Soil Testing Program*

## **Previous Poundstone Award Winners**

2001 -- Ellen Marshall -- Feed/Fertilizer Analytical Laboratory

2000 -- Sue Stone -- Data Processing

### **Poundstone Award Has Industry Support**

The Division of Regulatory Services wishes to express its appreciation to the AgriBusiness Association of Kentucky, the Kentucky Feed and Grain Association and the Kentucky Seed Improvement Association for their support of the Poundstone Award. It is especially gratifying that these associations participate in the recognition of our outstanding staff. This speaks well of the excellent relationship and support by the regulated industries for our regulatory and service programs. Working together has been a successful approach that has greatly benefited the industry and Kentucky consumers.

*Eli Miller -- Director*

## **FDA Proposes Bioterrorism Regulations on Facility Registration**

On January 29, 2003, the Food and Drug Administration (FDA) announced its proposed regulations for two food industry related provisions. One relates to the registration of food facilities and the other addresses the requirements for prior notice of food imports. Both of these items are part of the Public Health Security and Bioterrorism Response Act. The Act was signed into law last year as part of the United States' efforts to improve homeland security.

Proposed regulations for the registration of food facilities will have a direct impact on many firms involved in Kentucky's feed and dairy industries. The FDA's press release concerning this issue is included in this newsletter in an effort to keep Kentucky registrants and licensees better informed of a wide array of issues that may potentially impact their operations.

Biosecurity is of enormous importance to all of agriculture. Those involved in the feed and dairy industries are particularly concerned with biosecurity issues. The proposed regulations cited in FDA's press release will impact a number of Kentucky's feed and dairy industry businesses. A number of independent industry groups are reviewing this proposal in an effort to determine exactly how it will impact their particular industry segment. Those who have questions concerning this matter may wish choose to work through these groups or you may provide comments to FDA directly as indicated in the following press release.

### **FDA PROPOSES REGULATION FOR REGISTERING FOOD FACILITIES**

FDA today (*January 29, 2003*) announced a proposed regulation that would require domestic and foreign food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the agency by December 12, 2003. The proposal is one of the keystones in implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This act provided FDA new authority in protecting the nation's food supply against terrorist acts and other threats.

"Improving the FDA's food safety inspection, detection and monitoring capabilities is and has been a top priority of the Department even before the events of 9/11. Since then we have taken strong steps to enhance the FDA's ability to make our food supply safer," said Secretary of Health and Human Services Tommy G. Thompson. "This FDA effort is the latest in a series of measures we are taking to build stronger safeguards for the American people."

"This measure will bolster our ability to regulate effectively the more than 400,000 domestic and

foreign facilities that deal with food within our country," said FDA Commissioner Dr. Mark B. McClellan. "Our ability to efficiently and effectively help protect the nation's food supply is a critical part in our agency's counterterrorism mission. Thanks to the efforts of Senators Gregg and Kennedy, and Representatives Tauzin and Dingell, the Bioterrorism Act gives FDA this important new authority."

Under the proposal all domestic food facilities would be required to register whether or not food from the facility enters interstate commerce. Except for specific exemptions, the new regulation would apply to all facilities for all foods and animal feed products regulated by FDA, including dietary supplements, infant formula, beverages (including alcoholic beverages), and food additives.

The proposed regulation would require the owner, operator, or agent in charge of a domestic or foreign facility to submit a registration to FDA, including the name and address of each facility at which, and

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## **Proposed Change in Kentucky Fertilizer Tonnage Reporting Frequency**

The current Kentucky fertilizer law requires two kinds of tonnage reports: (1) a monthly sales data report for all registrants/licensee and (2) an inspection fee report either monthly, quarterly, or semi-annually. This has always caused confusion as to which report is due because of the misunderstood dual reporting requirement. A change has been proposed to simplify the tonnage reporting system and require only quarterly reporting. A bill has been introduced into this session of the Kentucky General Assembly that would effect this change.

The proposed change is to KRS 250.381 and KRS 250.386, the tonnage reporting sections of the Kentucky Fertilizer Law

### Summary of Change

1. Consolidates all tonnage reporting into one report per quarter.
2. Eliminates 'monthly' reporting of fertilizer sales.
3. Retains reporting by county, by grade, by form of distribution, and by use (farm or non-farm).

### Advantages

1. Reduces sales data/consignment reports (monthly reports) required of registrants/licensees from 12 per year to four (4) per year.
2. For previous 'monthly' reporters, reduces payments from 12 to four (4) per year.
3. Allows the Division of Regulatory Services to more accurately track inspection fee income by fiscal year.
4. Eliminates the semi-annual inspection fee report.
5. Standardizes quarterly reporting within the Division of Regulatory Services for all the regulatory programs (feed, seed, milk and fertilizer).

### Disadvantages

1. For previous 'semi-annual' reporters, increases payments from two (2) per year to four (4) per year.
2. Late reports are penalized after 45 days rather than 50 days.

Specific wording of the change may be found on our web-site (<http://www.rs.uky.edu/fert/fert.htm>) or by calling (859) 257-2668 and requesting a copy.

*D.L. Terry -- Fertilizer Regulatory Program*

## 2003 Kentucky Dairy Conference

Be sure to mark your calendar for the 2003 Kentucky Dairy Conference scheduled on Tuesday, March 4, 2003 at the Cave City Convention Center. It all starts at 8:30 a.m. Central Time with registration and the opportunity to view exhibits. The formal program begins at 9:30 a.m.

This year's conference will provide producers and other dairy industry folks with pertinent updates relating to current issues impacting Kentucky's dairy industry. The agenda promises to provide producers with information that they can take home to implement and potentially improve their operations. The conference is also a good time to make contacts with other producers and industry support personnel to share ideas for everyone's benefit.

A copy of the program and registration form can be obtained on our website ([www.uky.edu/Agriculture/RegulatoryServices/welcome.html](http://www.uky.edu/Agriculture/RegulatoryServices/welcome.html)) or by contacting Extension Dairy Specialist Bill Crist at (859) 257-7543.

Help spread the word about this event to make the 2003 Kentucky Dairy Conference a success!

*Chris Thompson -- Milk Regulatory Program*

## Pet Food Analysis

January was the time for pet foods to be sampled by the inspectors and submitted to the analytical laboratory. This year the lab received about 900 pet food samples. Several analysis are performed on these materials.

Analysis include: crude protein, crude fat, crude fiber, lysine, salt, calcium, phosphorus, copper, magnesium, manganese, potassium, zinc, ash and moisture.

A record number of cans, 250, of food materials were processed for analysis in January. The dry food materials and the treats and seeds will be analyzed in February. A variety of the samples were tested this year. The materials included food products for birds, turtles, fish, ferrets, gerbils, dogs and cats, etc.

The forms of these materials are interesting -- rawhide, gravy, seeds, soft and hard



treats, milk, flakes, bones, nuggets -- all those appealing forms of food were submitted this year.

This time of year and all these materials makes for interesting and challenging work in the lab.

*Mel Bryant and David Tompkins -- Feed/Fertilizer Analytical Lab*

## Kentucky Quality Dairy Producer Award

The Dairy Products Association of Kentucky (DPAK) will be presenting the Kentucky Quality Dairy Producer Award at the Kentucky State Fair's Dairy Recognition Dinner in August. Last year was the first time this type of honor was given to a Kentucky dairy producer and it was viewed as a great success. The purpose of the award is to recognize the Kentucky dairy producer who best portrays the production of high quality milk.

The 2003 award's criteria are to be based on producer data derived from April 1, 2002 through March 30, 2003. All nominees are required to possess valid permits from the Cabinet for Health Services Milk Safety Branch throughout this period. Nomination forms should be postmarked or delivered to DPAK no later than June 15, 2003.

Applications may be submitted by producers themselves or by professionals who serve the dairy industry such as dairy field representatives, veterinarians, extension personnel, milk haulers and others. These individuals should work closely with producers to help ensure the accuracy of the information reported on the nomination form. Copies of the nomination form can be obtained at Regulatory Services Milk Program web-site ([www.uky.edu/Agriculture/RegulatoryServices/welcome.html](http://www.uky.edu/Agriculture/RegulatoryServices/welcome.html)) or by contacting David Klee, Executive Director of DPAK at (502) 867-7843.

Now is the time to start thinking about who you feel will be a good candidate for this prestigious dairy producer award. Be sure to nominate the Kentucky dairy producer who you feel best exemplifies the production of high quality, wholesome milk!

*Chris Thompson -- Milk Regulatory Program*

## Getting Seed Ready for Spring Sales

If you haven't checked your seed stock yet this year – do it now! Our inspection staff is currently visiting locations checking seed supplies. A little attention to your carryover stock now can save you additional work and headaches later.

Identify all your seed and check the test date. Remember the test date on your seed is good for nine months, excluding the month it was tested. Seed that is out of date, or soon will be, must be tested for germination and relabeled according to the results. Remember that uncertified seed must have a total germination of at least 60%. Certified seed must have a germination equal to the KY certification standard for that seed kind, regardless of where the seed was grown.

The seed sample you send in for testing needs to be an accurate representation of the lot, so don't sample just one bag. Send your sample to our lab or another testing lab with the seed kind, variety, lot number and any treatment information, also indicating the tests you want performed (usually a germination test only for carryover seed). Our lab does provide testing envelopes free of charge, just call and request some if needed or you can use a bag or envelope of your own. When sending more than one sample, be sure each is securely sealed to prevent contamination between samples and that the samples fit tightly in the shipping container.

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## Target Ingredient Announcement AAFCO Recommended Enforcement Event Enforcement Strategy for Marketed Ingredients (ESMI) Working Group

The Association of American Feed Control Officials (AAFCO) goals include the development and implementation of uniform and equitable laws, regulations, standards, definitions and enforcement policies for the regulated industry. Unfortunately, part of the job involves enforcement activities. The association announced that a target ingredient was selected for a uniform enforcement event. The target ingredient, comfrey, has been shown to be a health and safety concern for animals and humans, prompting regulatory action by the United States, Canada and Germany. Based on my best information, this ingredient is usually found in horse supplements. Below is the actual announcement as extracted from the AAFCO web site (<http://www.aafco.org/>).

*During the AAFCO Annual Meeting in August 2002, the Enforcement Strategy for Marketed Ingredients (ESMI) Working Group announced the target ingredient recommended for a future regulatory enforcement event. The target ingredient, comfrey, has been shown to be a health and safety concern for animals and humans, prompting regulatory action by the United States, Canada and Germany. Comfrey does not meet any of the recognized criteria for use as an animal feed ingredient or animal feed.*

*Comfrey was identified by the ESMI Working Group based on the following published scientific information provided by the United States Food and Drug Administration (FDA), Center for Veterinary Medicine with references provided upon request:*

*The leaf and root of the comfrey (*Symphytum officinale*) plant have been used in supplements. Supplement use has been orally for ulcers, diarrhea, cough, bronchitis, and rheumatism or topically for the treatment of inflammation, arthritis, wounds, and bruises. This supplement has been banned in Germany and Canada due to safety concerns.*

*Comfrey has shown to be hepatotoxic in both humans and rats. The toxic compounds found are pyrrolizidine alkaloids (8 have been identified), which include lasiocarpine and symphytine. The highest content of these substances were found in products containing bulk comfrey root or leaf.*

*Pyrrolizidine alkaloids have also been associated with lung and liver cancer. The pri-*

*mary liver ailment associated with comfrey consumption is veno-occlusive disease (a form of Budd-Chiari syndrome), a non-thrombotic destruction of small hepatic veins leading to cirrhosis and eventual liver failure. Consumption of 85 mg pyrrolizidine alkaloids (15 µg/kg BW/d) for 6 months resulted in venocclusive disease in a 49-year old woman. Signs of liver toxicity have been seen in rats consuming low doses of comfrey (50mg/kg BW three times a week for three weeks) which included loss of sinusoidal lining cells, sinusoids filled with cellular debris (hepatocyte organelles and red blood cells), and narrowing of terminal hepatic venules.*

*Pyrrolizidine alkaloids extracted from comfrey were shown to damage chromosomes when administered to human lymphocytes at concentrations of 140 µg/mL and 1400 µg/mL. At these concentrations, sister-chromatid exchange and chromosome aberra-*

*Continued on pg. 9*

## Update on Ethylenediamine Dihydroiodide (EDDI) as a Source of Iodine

Several feed manufacturers in the state have inquired about the use of Ethylenediamine Dihydroiodide (EDDI) as a source of iodine in salt/mineral mixtures and other animal feeds. Some of manufacturers are aware that FDA issued a revised Compliance Policy Guide on the use of EDDI on 5/1/2000. The revised CPG can be found on the Internet at [http://www.fda.gov/ora/compliance\\_ref/cpg/cpgvet/cpg651-100.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg651-100.html). Guidance documents represent FDA's current thinking on animal products containing unapproved new drugs under the provisions of the Federal Food Drug and Cosmetic Act.

EDDI has been incorporated into animal feed and drug products for many years for both nutritional and therapeutic purposes. It has been formulated in salt/mineral mixtures and other animal feeds. EDDI has been used as a supplemental source of iodine and is considered generally recognized as safe (GRAS) for nutritional purposes when used at levels consistent with good feeding practices. EDDI products also have been marketed with claims for the treatment and prevention of certain diseases in several animal species, but primarily for "foot rot," soft tissue "lumpy jaw" and "wooden tongue" in cattle. However, all such EDDI products (including feeds) bearing therapeutic claims (other than the prevention of iodine deficiency) are considered adulterated and subject to regulatory action.

Cattle products that are not labeled with disease treatment or prevention claims and are formulated to provide 50 mg or more/head/day of EDDI will be evaluated on a case-by-case basis. After a review by state or federal regulatory agencies the products may be deemed adulterated. The previous policy guide indicated levels of EDDI between 10 and 50 mg/head/day would be reviewed on a case-by-case basis. Thus, the revised allowed level of EDDI before a review would be conducted has been increased from 10 mg/head/day up to a maximum level of 49.9 mg/head/day.

*Steve Traylor -- Feed Regulatory Program*

### Spring Seed Sales continued from pg. 6

As new seed is coming in to your location, take a few minutes to check it. Make certain you receive the kind and variety you ordered and that it is properly tagged. Do not accept seed that does not have identification on it – each container or bag must have a label. Read the labels to make certain all the necessary information is there – seed kind and variety, lot number, pure seed, inert matter, weed seed, crop seed, noxious weeds, germination (with hard seed, if appropriate) origin and test date as well as a current address.

Take a few minutes to check your records, making sure you have the appropriate

permit and registration for your location. Also, review any stop sale orders from last year and make sure all have been resolved. If you have any seed under stop sale order, do not sell it! Determine the reason for the stop and take action to correct the violation – usually relabeling the lot will correct the violation.

Questions about permits, registration or stop sales can be directed to David Buckingham. Questions about seed testing and service requests can be directed to Cindy Finneseth.

*David Buckingham -- Seed Regulatory Program  
Cindy Finneseth -- Seed Testing Program*

## 2003 AAFCO OFFICIAL PUBLICATION

The Official Publication of the Association of American Feed Control Officials 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 with address, e-mail, telephone and 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 2003 Official Publication is available and orders can be sent to:

Sharon Senesac, Asst. Secretary-Treasurer  
P.O. Box 478  
Oxford, IN 47971  
(765) 385-1029, Fax (765) 385-1032  
E-mail: [Sharon@localline.com](mailto:Sharon@localline.com)

Visit the AAFCO web site [www.aaftco.org](http://www.aaftco.org) for the order form and other information.

Steve Traylor -- Feed Regulatory Program

### ESMI continued from pg. 7

*tions were observed. On July 6, 2001, the FDA advised dietary supplement manufacturers that comfrey should not be used in dietary supplements due to safety concerns.*

*AAFCO recommended to feed control officials that an enforcement event occur to clarify the regulatory status of ingredients sold for consumption by animals as animal feed, including livestock feed and pet food. All feed ingredients must be shown to be safe and efficacious for their*

*intended use prior to distribution. Feed manufacturers have several methods for meeting this requirement that are summarized in an ingredient fact sheet entitled, "Options Available for Acceptance of a Proposed Feed Ingredient", available on the AAFCO Website. Feed ingredients not recognized or acceptable for their intended purpose may be subject to regulatory action by the feed control official and the FDA.*

Steve Traylor -- Feed Regulatory Program

## **FDA Proposal continued from pg. 3**

### **FDA Proposes Bioterrorism Regulations on Facility Registration**

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*Chris Thompson -- Milk Regulatory Program  
Steve Traylor -- Feed Regulatory Program*

## **2003 AAPFCO Official Publication No. 56 Now Available**

The Association of American Plant Food Control Officials' Publication No. 56 has the latest changes to all the model documents and much more. All persons concerned with fertilizer regulatory activities -- both regulatory and industry -- should own a copy of this valuable resource. A sampling of what this publication includes follows:

- Board of Directors, Committee and Task Force Chairperson and Member Lists
- AAPFCO Bylaws and Policy Statements
- Proceedings from the 56th Annual Meeting
- Officially Adopted Documents
  - State Fertilizer Bill
  - Agriculture Liming Materials Bill
  - Soil Amendment Bill
  - State Ammonia Bill
  - Chemigation Bill
  - Horticultural Growing Media Labeling Bill
- Committee and Investigator Reports
- Board of Directors and Treasurer Reports
- Registrant List for 2002 Annual Meeting
- Control Official and Industry Liaison Directories

Also available from AAPFCO are the Inspection Manual and Inspector Video. For ordering and payment information contact:

Joel Padmore  
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NC Dept. Of Agriculture  
4000 Reedy Creek Road  
Raleigh, NC 27607-6468  
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FAX (919) 733-6801  
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An order form is available on the AAPFCO website at: <http://www.aapfco.org/pubord.pdf>

*D.L. Terry -- Fertilizer Regulatory Program*

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