Regulatory Services News

Vol. 56, No. 4 Feed - Fertilizer - Milk - Seed - Seed Testing - Soil Testing Winter 2013

Director's Digest– Winter 2013

The Food and Drug Administration has released their much anticipated proposals for the feed industry in response to the Food Safety Modernization Act (FSMA). The proposal was published on October 29 with a proposed 120 day comment period and could be implemented 60 days after the close of the comment period. At the earliest, these new rules could take effect in late spring of 2014. In reality, it will probably be later but implementation will occur in the next year or so. If you are in the livestock or pet food business, this will mean increased regulation. A short summary of the proposal may be found at the following link: <u>http://</u> <u>www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM368997.pdf</u>. The following quote from this summary indicates what this may mean to your business:

"Facilities producing animal food would be required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results, and specify what actions would be taken to correct problems that arise. The proposed rule would also establish certain Current Good Manufacturing Practices (CGMPs) that specifically address animal food."

This is in the comment phase and I encourage you to read the summary and make comments to the FDA about the proposal. To me, failure to comment shows support. Please let them know how this will impact your business. It is proposed that inspections in regards to the new rules will be carried out by a combination of state and FDA inspectors similar to what is being done now with BSE inspections. As these changes become law, please let us know what we can do to help your company be compliant.

Our proposed changes in the seed regulations dealing with seed service testing fees and inspection fees are set to take effect on January 1, 2014. Steve McMurry has summarized the new regulations in this newsletter. Thank you for supporting us in these much needed changes.

I hope each of you will take this time of year to think about all you have to be thankful for and I hope you have a great holiday season.

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Improving Chemical Facility Safety and Security Public Listening Sessions

The Department of Homeland Security is now conducting public listening sessions on Executive Order 13650, Improving Chemical Facility Safety and Security. At these sessions the working group will share an overview of the various sections of the EO and the progress made to date on each. In particular, they are interested in hearing from the stakeholders described in the EO: chemical producers, chemical storage companies, agricultural supply companies, State and local regulators, chemical critical infrastructure owners and operators, first responders, labor organizations representing affected workers, environmental and community groups, and consensus standards organizations. Attendees will have an opportunity to provide individual input on the process and the specific areas in the EO. The Working Group is interested in hearing specific ideas and solutions on improving operational coordination with States, Tribes, and local partners; enhanced information collection and sharing; modernizing regulations, guidance, and policies; and identifying best practices in chemical facility safety and security.

Written comments by in-person attendees to the listening sessions and teleconference participants may be submitted to <u>eo.chemical@hq.dhs.gov.</u> Please note that additional listening sessions will be held at the locations below. Information on these sessions will be posted to the Federal Register. Once posted to the Federal Register, individuals will be able to submit comments to the docket associated with the notice.

For general information on the EO, please check the <u>http://www.dhs.gov/topic/chemical-security</u>. Please feel free to contact <u>eo.chemical@hq.dhs.gov</u> for questions.

Anticipated future Schedule for EO Listening Sessions are below: please check the websites for additional information on how to access the Webinars.

Date	Location
November 25, 2013	Webinar
December 11, 2013	Orlando, FL
December 16, 2013	Webinar
January 7, 2014	California
Week of January 20, 2014	Houston, TX

Stephen McMurry, Director Fertilizer and Seed Program

If you know of anyone that you feel would benefit by receiving the Regulatory Services Newsletter, please have them visit the Division's website at www.rs.uky.edu, navigate to the Newsletter page and submit their contact information.

Changes to the Kentucky Agricultural Experiment Station Seed Laboratory Fee Schedule

The fee schedule currently used by the Seed Laboratory at the University of Kentucky is established in a regulation under the Kentucky Seed Law. Statute KRS 250.081(1)c6 of the Kentucky Seed Law requires the Director of the Agricultural Experiment Station to promulgate administrative regulations establishing charges for tests of samples submitted to the Kentucky Agricultural Experiment Station Seed Laboratory for service testing. We have been using the same fee schedule established in regulation 12 KAR 1:155 since 1994. Due to significant changes in cost associated with the various tests we conduct, our Division proposed an updated regulation containing a new fee schedule. The new fees were established based on an analysis of actual costs and a comparison to charges from other seed test laboratories. Our goals were to develop a fee structure to recover more of our actual costs and to remain affordable to the Kentucky seed industry and producers

The new regulation was approved by the Kentucky State Legislature this fall and is shown below. The new fee schedule will take effect on samples submitted after January 1, 2014.

Kind of Seed	Complete Test	Purity and Nox- ious Weed Seed Test	Germination Only
Group 1: Corn and soybeans	\$18.00	\$9.00	\$11.00
Group 2: Small grains	\$14.00	\$7.00	\$9.00
Group 3: Tobacco	\$21.00	\$16.00	\$11.00
Group 4: Clovers, alfalfas, and lespedezas	\$18.00	\$9.00	\$11.00
Group 5: Lawn and forage grasses	\$20.00	\$14.00	\$12.00
Group 6: Native grasses, flow- ers, and forbs	\$40.00	\$30.00	\$30.00
Group 7: Vegetables	\$18.00	\$13.00	\$12.00
Group 8: Ornamentals (trees, shrubs, and flowers) and herbs	\$30.00	\$18.00	\$20.00

- (b) Nonresidents shall be assessed an additional charge of fifteen (15) dollars per sample.
- (c) A complete test shall include a purity analysis, a noxious weed seed examination (for Kentucky only), and a germination test.
- (d) A purity and noxious weed test shall include a purity analysis and a noxious weed seed examination (for only those seed designated as noxious in Kentucky).
- (e) In ryegrass samples, a complete test shall be assessed a charge of twenty-five (25) dollars and shall include a fluorescence test which distinguishes perennial ryegrass seed and annual ryegrass seed.
- (f) Mixtures, difficult, or dirty samples may be charged an additional forty (40) dollars per hour for extra separation time.
- (g) Mixtures submitted for germination testing shall be charged a fifteen (15) dollar separation fee. Each component over five (5) percent of the total in mixtures shall be charged individually for germination testing.
- (h) Rush service may be provided upon request at an additional charge of twenty-five (25) dollars per sample.
- (i) Samples of coated, encrusted, pelleted, film-coated, or treated seed shall be charged an additional ten (10) dollars for hand washing and disposal of toxic substances.

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- (j) The schedule of charges for special tests shall be:
 - 1. Noxious weed seed examinations:
 - a. Kentucky only: ten (10) dollars;
 - b. Other states: fifteen (15) dollars per state; and
 - c. All states: fifty (50) dollars;
 - 2. Moisture test: eight (8) dollars;
 - 3. Seed count per pound: ten (10) dollars;
 - 4. Varietal identification:
 - a. Soybean hypocotyl color test: fifteen (15) dollars;
 - b. Phenol test of wheat: eighteen (18) dollars; and
 - c. Peroxidase test of soybean: eighteen (18) dollars;
 - 5. Vigor tests:
 - a. Accelerated aging: eighteen (18) dollars;
 - b. Cold test: eighteen (18) dollars; and
 - c. Conductivity: eighteen (18) dollars;
 - 6. Tetrazolium test:
 - a. Groups 1 and 2: eighteen (18) dollars;
 - b. Groups 4, 5, and 7: thirty (30) dollars; and
 - c. Groups 3, 6, and 8: forty (40) dollars;
 - 7. Seed or plant tall fescue endophyte. One (1) to 100 specimens: \$100;
 - 8. Biotechnology trait identification. Herbicide bioassay: twenty-five (25) dollars; and
 - 9. Reexamination of a sample to secure information not requested initially, or any analysis or test to obtain information not specifically required by the Kentucky Seed Law, KRS 250.021 to 250.111 and 12 KAR Chapter 1, shall be assessed forty (40) dollars per hour for analytical time.
- (k) Testing performed in compliance with International Seed Testing Association (ISTA) rules shall be charged fifteen (15) dollars in addition to test fees.
- (1) Testing performed in compliance with Canadian Methods and Procedures (M & P) for Testing Seed shall be charged eighteen (18) dollars in addition to test fees.
- (m) Charges for kinds not listed in this subsection shall be in accord with charges made for other kinds of seed of similar size.

Changes to the Kentucky Seed Law Regulations

This past year the Division has been working on updating the Kentucky Seed Law Regulations. We are pleased that these are now complete and will go into effect January 1, 2014. Below is a brief description of the changes. The complete regulations can be found on the web at <u>www.rs.uky.edu/seed/law/index.php.</u>

12 KAR 1:116 Sampling, analyzing, testing, and tolerances

Rules for testing seed were updated from 2005 to 2012 standards developed by the Association of Official Seed Analysts.

12 KAR 1:135 Tags available for purchase

When a company does not want to purchase a permit to label seed on their own, they can buy tags from us at the same rate as reporting seed as if they had a permit. Changes in this regulation correspond to the change in which permitted companies report sales on a quarterly basis.

12 KAR 1:140 Permits, reports, and fees for companies using their own tags

Forms were updated and have the following changes in fees for regulatory compliance

- a. All seed will now be reported with the same fee structure
- b. Soybean and corn can be reported by the number of "units" sold. Corn has 80,000 seeds per unit and soybean has 140,000 seeds per unit.

The new form is shown on next page.

12 KAR 1:145 <u>Registration of agricultural seed dealers, noncertified custom seed</u> <u>conditioners, certified seed growers, and certified seed conditioners</u>

The forms for seed dealers and seed conditioners have been updated.

12 KAR 1:150 Stop sale orders

The stop sale form was removed and incorporated only be reference. This is an internal form that may be modified to provide the capability of delivering it via electronic means when necessary.

12 KAR 1:155 Fee Schedule for samples submitted for testing

The fee schedule currently used by the Seed Laboratory at the University of Kentucky for samples submitted for testing are established in regulation 12 KAR 1:155 of the Kentucky Seed Law. We have been using the same fee schedule established in the regulation since 1994. Due to significant changes in cost associated with the various tests we conduct, our Division proposed an updated regulation containing a new fee schedule. The new fees were established based on an analysis of actual costs and a comparison to charges from other seed test laboratories. Our goals were to develop a fee structure to recover more of our actual costs and to remain affordable to the Kentucky seed industry and producers. The new fee schedule is attached (provide file name) and will take effect on samples submitted after January 1, 2014.

12 KAR 1:165 Germination standards for vegetable seed

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 our office at (859) 257-2785. You can also access Regulatory Services News on the Internet at http://www.rs.uky.edu.

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Division of Regulatory Services

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Feed Program Update: Product Registration and Inspection Fees

As Director of the Feed Program for Regulatory Services, product registration and inspection fees fall under my purview. Ensuring that all products offered for sale in the state of Kentucky are properly registered and that inspection fees are paid are two responsibilities we take very seriously.

Registration

All facilities manufacturing feed and all commercial feed distributed in the state must be registered. The following Kentucky Statue addresses this requirement.

250.511 Registration of commercial feed manufacturing facilities.

1.No person shall manufacture a commercial feed in this state, unless he has filed with the director on forms provided by the director, his name, place of business, and location of each manufacturing facility in this state.

2. No person shall distribute in this state a commercial feed, except a customer formula feed, which has not been registered pursuant to the provisions of this section. The application for registration shall be submitted in the manner prescribed by the director. Upon approval by the director, the registration shall be issued to the applicant. A registration shall continue in effect unless it is canceled by the registrant or unless it is canceled by the director pursuant to subsection (3) of this section. The director by administrative regulation may exempt the manufacturer or distributor named on the label from the requirement for registration of each feed distributed in the state.

The failure or refusal to register in accordance with KRS 250.511 is a prohibited act (250.551, 4) and subject to regulatory action against the manufacturer.

Inspection Fees

Our feed law in Kentucky requires the collection of inspection fees on all commercial feeds distributed in the state. Customer formula feeds are also subject to the same inspection fee as commercial feeds. If inspection fees have previously been paid on ingredients or commercial feeds used in a customer formula feed, that portion of the feed is not subject to a second inspection fee. Feed distributed only in packages of 10 pounds or less are handled differently with an annual fee rather than an inspection or tonnage fee.

250.561 Inspection fee.

1. An inspection fee at the rate of thirty-five cents (\$0.35) per ton shall be paid on commercial feeds distributed in this state by the person whose name appears on the label as the manufacturer, guarantor, or distributor, except that a person other than the manufacturer, guarantor, or distributor may assume liability for the inspection fee, subject to the following:

A. No fee shall be paid on a commercial feed if the payment has been made by a previous distributor;

B. No fee shall be paid on customer formula feeds if the inspection fee is paid on the commercial feeds which are used as ingredients and any exempt commodities, such as whole grain, furnished by the final purchaser. An exempt commodity offered for sale by the custom formula feed distributor for the intended use as an ingredient in the manufacture of custom formula feed is subject to the inspection fee. If the fee has already been paid on the commercial feeds, credit shall be given for that

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payment. No farmer-owned exempt commodity shall be subject to a fee;

- C. No fee shall be paid on commercial feeds which are used as ingredients for the manufacture of commercial feeds which are registered. If the fee has already been paid, credit shall be given for that payment;
- D. In the case of a commercial feed which is distributed in the state to the final purchaser only in a package weight of ten (10) pounds or less, an annual fee of fifty dollars (\$50) shall be paid in lieu of the inspection fee specified above;
- E. In the case of distillers' wet grains and other distillers' by-products containing more than seventyfive percent (75%) moisture and brewers' wet grains and whey distributed without further processing to the final purchaser for consumption by the purchaser's livestock, the inspection fee shall be five cents (\$0.05) per ton; and
- F. The minimum inspection fee for a feed registrant or a custom formula feed distributor shall be twenty five dollars (\$25) per quarter.

Complying with Kentucky law regarding product registration and inspection fee paid is a requirement of firms wishing to do business in the state. When all firms follow the law, we maintain a level playing field and promote fair competition. We are always available to answer questions regarding registration, inspection fees, and tonnage reports to assist firms in complying with Kentucky law.

Dr. Alan Harrison – Director Feed and Milk Programs

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RETURN SERVICE REQUESTED



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