# Regulatory Services News

Vol. 55, No. 4 Feed - Fertilizer - Milk - Seed - Seed Testing - Soil Winter 2012

Director's Digest

Dry, hot weather this past summer has made for an interesting fall here at Regulatory Services. Our inspectors have pulled several samples of shelled corn for mycotoxin analyses. Of roughly 90 samples pulled, we are showing 18.5% positive for aflatoxin with 12% of the total being above 20 ppb. Interest was expressed for Kentucky to apply for a blending waiver from FDA as has been done by at least 5 other states. The waiver allows blending corn with a high concentration of aflatoxin with corn of lesser or no aflatoxin content to obtain levels below 300 ppb. This blended corn can be labeled for feeding to mature poultry, breeding swine, finishing swine over 100 pounds, breeding cattle and finishing cattle. This blended corn may not be fed to dairy cattle or young animals. We received this waiver from FDA on October 12 and it is good until December 31, 2012. Anyone wishing to sell blended corn must register with Regulatory Services and the forms are available on our website.

I would caution all feed suppliers to be cautious of any corn or corn byproduct feeds they are purchasing. Be knowledgeable of any potential mycotoxin contamination and do what testing you need to protect yourself. Bargains may turn out to be pretty costly if these bargains contain high concentrations of mycotoxins.

As I mentioned in the last newsletter, Regulatory Services is intent on providing educational services to those we regulate. As a part of this, we are reviewing our feed mailing list and will send out a letter announcing our "feed hotlist". When there is information on topics such as mycotoxin contamination, FDA announcements, labeling issues or other information we feel beneficial, we want to be able to get this information out in a timely manner. Participation in this listing is strictly voluntary and email addresses provided will not be given to any entity outside of Regulatory Services. This listing is not restricted to one person per business so please feel free to add anyone you feel would benefit. Signup for this service is already available on our website at www.rs.uky.edu. If you visit our website, please also sign up to receive our newsletter electronically to help us save on printing costs and receive your newsletter much quicker.

I hope everyone has a Merry Christmas and a great crop year in 2013.

Darrell D. Johnson-Executive Director Regulatory Services

**What's inside...**



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**Electronic Delivery of the newsletter is starting in spring of 2013**

To reduce printing, paper and postage costs, Regulatory Services News is going to electronic. We'll now deliver right to your email address.

**To receive the quarterly newsletter in electronic format, please visit the Division's website at www.rs.uky.edu, navigate to the Newsletter page and submit your contact information.**

Newsletter editions dating to 2001 are available online.

While we at The Division of Regulatory Services do not wish to exclude anyone that wants to receive the newsletter by mail, we ask that you fill out the following form and return to us and we will be happy to send a printed copy by mail.

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Name:_____

Company:_____

Address:_____

City:_____State:_____Zip:_____

Phone:_____

Fax:_____

Company Type: Feed ___ Fertilizer _____ Seed _____ Milk _____

Please mail to: Regulatory News Letter
ATT: Tony Benge
103 Regulatory Services Building
Lexington, KY 40546-0275

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.

Bulk Wheat Information:

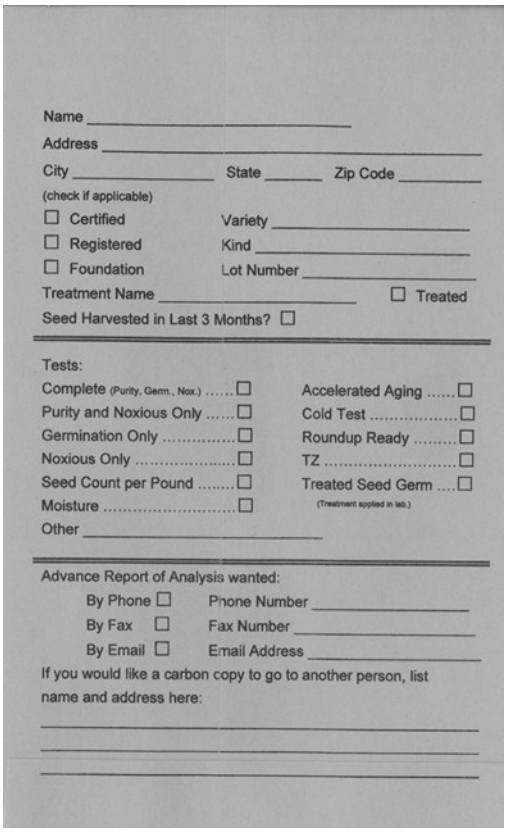
In regions of the state, it is not uncommon for agricultural retailers to offer bulk cover crop wheat for sale. Offering bulk wheat seed to purchasers is often the only time of the year that some ag retailers distribute seed with their own name on the label. With this uniqueness in mind, let's briefly review for how to properly distribute bulk cover crop wheat.

First, the bulk bin containing the wheat must be properly labeled using a seed test from an accredited lab. The test results for bulk lots offered for sale should be kept on file as part of the seed lot record. Additionally, the firm's name appearing on the label is required to be a permitted agricultural seed labeler. Practically all ag retail firms will already possess an agricultural seed dealer registration. This means most firms simply need to complete the ag labeler permit application to be approved. Next, make sure you have an adequate supply of labels to provide customers when they purchase bulk seed.

Whether offered for sale in bags (traditional small bags or "mini-bulk bags) or in bulk, it is important to note that the Kentucky Seed Law requires proper labeling for all seed sold in our state. The label provides a wide range of valuable information to inform purchasers about the quality and characteristics of seed. One of the most important items identified on the seed label is the variety statement. In Kentucky, practically all seeds sold with the intention of grain production are required to be identified with a variety name. Wheat is sometimes offered for sale as *variety unknown*. Keep in mind, *variety unknown* may only be used when the variety is truly unknown. This means the varietal traits producers seek when making wheat seed purchases will not be distinguishable when purchasing *variety unknown* wheat. The risks associated with *variety unknown* wheat is the main reason this type of seed is most often used for other purposes such as a cover crop and is not preferred for grain production.

Another important item to note is that all certified seed is required to be sold by variety name. Certified seed provides a further indication of high quality standards. Certified seed is easily distinguished with a blue label and specifies the seed has been produced under the strictest of quality assurance guidelines.

*When submitting newly harvested grain samples to the UK lab for service testing, be sure to identify that the seed has been harvested within the last three (3) months. This will alert the lab to perform a pre-chill prior to the germination test.*



Name _____

Address _____

City _____ State _____ Zip Code _____

(check if applicable)

☐ Certified Variety _____

☐ Registered Kind _____

☐ Foundation Lot Number _____

Treatment Name _____ ☐ Treated

Seed Harvested in Last 3 Months? ☐

Tests:

Complete (Purity, Germ., Nox.) ..... ☐ Accelerated Aging ..... ☐

Purity and Noxious Only ..... ☐ Cold Test ..... ☐

Germination Only ..... ☐ Roundup Ready ..... ☐

Noxious Only ..... ☐ TZ ..... ☐

Seed Count per Pound ..... ☐ Treated Seed Germ .... ☐

Moisture ..... ☐ (Treatment applied in lab.)

Other _____

Advance Report of Analysis wanted:

By Phone ☐ Phone Number _____

By Fax ☐ Fax Number _____

By Email ☐ Email Address _____

If you would like a carbon copy to go to another person, list name and address here:

_____

_____

_____

Terry Prather-Interim Seed Coordinator

**Position Changes in Regulatory Services**

The Division of Regulatory Services is going through a reorganization to deal with budget cuts and to increase efficiency. As part of this reorganization, the Seed and Fertilizer programs are being combined as well as the Feed and Milk programs. The manager of the Soils Lab will also be overall manager of all labs. In addition, there will be a Quality Control Coordinator and Assistant Lab Manager. Three of these positions were filled as of November 1, 2012 and the other two should be filled shortly.

Mr. Steve McMurry is our new coordinator for the Fertilizer and Seed Programs. Steve has been directing the fertilizer program for four years and will now add the seed programs. He also has experience as an inspector and inspector coordinator. He will provide good leadership to both these programs. Mr. Terry Prather has been serving as interim Seed Regulatory Program Coordinator and will help Steve until the end of this year when he will reassume his inspector duties full time. Terry has done an outstanding job of keeping the Seed Regulatory Program going forward and his service is greatly appreciated.

Dr. Frank Sikora is now the Soils Lab/Lab Manager. Frank has served as coordinator of the soils lab for fourteen years and will now use his expertise in managing this lab to managing all our labs. Frank's experience will be valuable in insuring that our labs provide accurate results in a timely manner.

Dr. Sharon Webb is our new coordinator of Quality Control. Sharon has served as coordinator of the Instrument Analysis Program for five years. She will be overseeing quality control procedures for all our labs and moving us forward on ISO certification.

Applicants for the Feed/Milk Coordinator and the Assistant Lab Manager are currently being reviewed (early November) and these positions should be filled shortly. Reorganization is never easy but this should make our Division stronger and we appreciate the above talented individuals stepping up and filling these important new positions.

*Darrell Johnson-Director*

**Changes in BT Registration**

As of October 22, 2012 all food/feed facilities required to register with FDA under the Bioterrorism Act must renew their registrations with FDA. BT registration is now a biennial requirement. Following is an **excerpt** of an article on food/feed registration renewals from FDA's website. The complete article can be found at www.fda.gov this article contains information about the registration process as well as Frequently Asked Questions (FAQ's). Additional information regarding Registration Renewal may be found at http://www.fda.gov/Food/Food Safety/FSMA/ucm314178.htm.

**New Registration Mandates under the FDA Food Safety Modernization Act**

About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on Jan. 4, 2011, enables FDA to better protect public health by strengthening the food safety system. It recognizes that preventive control standards improve food safety only to the extent that producers and processors comply with them. Therefore, it will be necessary for FDA to provide oversight, ensure compliance with requirements and respond effectively when problems emerge.

Building a new food safety system based on prevention will take time, and FDA is creating a process for getting this work done. Congress has established specific implementation dates in the legislation. The funding the Agency gets each year, which affects staffing and vital operations, will affect how quickly FDA can put this legislation into effect. FDA is committed to implementing the requirements through an open process with opportunity for input from all stakeholders.

FSMA amended section 415 of the Federal Food, Drug, and Cosmetics Act (FD&C Act) [21 U.S.C. § 350d], which requires domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the U.S. to register with FDA. The FSMA amendments to section 415 of the FD&C Act are described below. These amendments are focused on improving the agency's ability to respond to a food-related emergency quickly and efficiently.

**IC.3.1 Does FSMA require a food facility to submit additional registration information to FDA in order for the facility to receive a food facility registration number?**



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Yes. Section 102 of FSMA amends section 415(a)(2) of the FD&C Act by requiring food facilities to submit registrations to FDA containing additional information. Specifically, a registration for a domestic facility is required to contain the e-mail address for the contact person of the facility, or for a foreign facility, the email address of the United States agent for the facility. All food facility registrations are required to contain an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. Additionally, if determined necessary by FDA, registrations are required to contain information regarding other applicable food categories, as determined appropriate by FDA, for foods manufactured/processed, packed, or held at registering facilities.

**IC.3.2 Will food facilities already registered with FDA under section 415 of the FD&C Act be required to renew their registrations?**
Yes. All food facilities that are required to register with FDA under section 415 of the FD&C Act must renew their registrations with FDA, as required by section 102 of FSMA. Registrants are required to submit registrations to FDA containing the information described in section 415(a)(2) of the FD&C Act, including the new information added by section 102 of FSMA. Biennial registration renewal for food facilities will be available on Monday, October 22, 2012. Please check FDA's website at www.access.fda.gov for more information, or sign-up for FSMA updates at www.fda.gov/FSMA. Additional information regarding Registration Renewal may be found at http://www.fda.gov/Food/FoodSafety/FSMA/ucm314178.htm.

**IC.3.3 Has the scope of who is required to register under section 415 of the FD&C Act changed?**
No. At this time, the same types of food facilities that were required to register with FDA under section 415 of the FD&C Act before FSMA are required to register with FDA and renew such registrations. Those facilities are domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. Section 103(c) of FSMA directs FDA to conduct a rulemaking to "clarify the activities that are included as part of the definition of the term 'facility' under such section 415 [of the FD&C Act]." The rule to clarify activities that are included as part of the definition of the term "facility" will be proposed as part of the rulemaking for the preventive controls regulation, as provided by section 103(c) of FSMA. This proposal will be published in the Federal Register when it is issued, and there will be an opportunity for public comment. For more information on preventive controls, please visit FDA's Preventive Standards page

**IC.3.5 What form do I use to renew a food facility registration?**
Registrants must use Form 3537 to register, update, or renew a registration. Facilities may register online via the Internet at www.fda.gov/furls, which operates during business hours from 7:00 am to 11:00 pm U.S. Eastern Time. Facilities may also register by mail or fax or for multiple submissions, by CD-ROM.
Registration by Paper (Mail or FAX) or CD-ROM

**IC.3.6 What information is required for food facility registration renewal?**
All mandatory fields on the Form 3537 must be complete in order to renew a food facility registration. This includes new or updated fields described in question IC.3.1. If using the online renewal process, existing registration information will be displayed for review and can be edited as necessary. All information submitted, in both mandatory and optional fields, must be true and accurate, and the registrant will be required to certify that all information submitted is true and accurate at the end of the registration process.

**IC.3.7 Am I required to renew a food facility registration online?**
No. Registrants can renew food facility registrations online or submit the paper Form 3537 by mail or fax. A business with multiple facilities may also renew a registration on a CD-ROM by mail. FDA encourages online registration renewal as a cost-effective, quick, and efficient means for food facility registration renewal. With online registration renewal, a registrant may review and edit existing registration information and add information. All of the mandatory data fields are required for the system to accept the renewal submission. After all required information has been entered, a registrant will receive confirmation of registration renewal.
Paper registration renewal likely will be a more costly and less efficient process to supply FDA with registration information and to provide food facilities with their registration renewal confirmations than online registration. As with online submissions, for paper submissions, all mandatory data fields must be completed. However, if your paper registration form contains errors or omissions, FDA will return it for corrections, which may require additional time to complete the registration process. As a result it may take longer to receive confirmation for paper registration renewals.
**IC.3.8 Is there a fee for registration, updating a registration, or renewal of registration?**
No. There is no fee associated with initial registration, updating a registration, or renewing a registration.

**IC.3.9 Do new food facilities need to wait until October 1st to register?**
No. The owner, operator, or agent in charge of a facility that begins to manufacture/process, pack, or hold food for consumption in the U.S. on or after December 12, 2003 must register before the facility begins such activities (21 C.F.R. 1.230). An owner, operator, or agent in charge of a facility may authorize an individual to register the facility on its behalf

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(21 C.F.R. 1.230). If a facility registers before October 1, 2012, the facility will still be required to renew its registration during the registration renewal period.

**IC.3.12 What happens if a facility fails to register?**
The failure to register your facility, update required elements, or cancel a registration in accordance with 21 CFR Part 1, Subpart H is a prohibited act under the FD&C Act (see 21 C.F.R. 1.241). If a foreign food facility is required to register with FDA, but fails to do so, food from that facility that is being imported or offered for import into the U.S. is subject to refusal under section 801(l) of the FD&C Act.

**IC.3.13 Will a food facility be issued a new registration number during the biennial registration renewal process?**
No. A food facility will not be issued a new registration number when it renews a current registration under the biennial registration renewal process.

**IC.3.14 When may FDA suspend the registration of a facility registered under section 415 of the FD&C Act?**
Under section 415(b) of the FD&C Act, if FDA determines that food manufactured, processed, packed, received, or held by a facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:

Created, caused or was otherwise responsible for such reasonable probability; OR
Knew of or had reason to know of such reasonable probability AND packed, received or held such food.

**IC.3.15 When are registered facilities subject to the suspension of registration provisions?**
Registered facilities became subject to the suspension of registration provisions in section 415(b) of the Federal Food Drug and Cosmetic Act on July 3, 2011; 180 days after the date of enactment of FSMA (January 4, 2011).

**IC.3.16 What is the effect of such a suspension?**
If the registration of a facility is suspended, no person can import or export food into the United States from such facility, offer to import or export food into the United States from such facility, or otherwise introduce food into interstate or intrastate commerce in the United States from such facility (section 415(b)(4) of the FD&C Act). This important authority will further help FDA ensure the safety and security of our nation's food supply.

**IC.3.17 Who may issue an order to suspend a facility's registration?**
The authority to issue an order to suspend a registration or to vacate an order of suspension may not be delegated by the Secretary of Health and Human Services to any officer or employee other than the FDA Commissioner (section 415(b)(7) of the FD&C Act).

**IC.3.18 Is there an opportunity for an informal hearing on suspension of registration?**
FDA will provide a registrant subject to a suspension of registration order with an opportunity for an informal hearing, to be held as soon as possible but not later than 2 business days after the issuance of the suspension of registration order, unless an alternate time period is agreed upon by FDA and registrant. The registrant will have an opportunity for an informal hearing on actions required for reinstatement of registration and why the registration that is subject to suspension should be reinstated. FDA will reinstate a registration if it determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration (section 415(b)(2) of the FD&C Act).

**IC.3.20 How may a suspension of registration order be vacated or modified?**

Upon a determination by FDA that adequate grounds do not exist to continue the suspension actions required by a suspension of registration order, or that such actions should be modified, FDA will vacate the order and reinstate the registration of the facility subject to the order, or modify the order, as appropriate (section 415(b)(3) of the FD&C Act).

**IC.3.21 Is FDA going to promulgate regulations on suspension of registration?**
Yes. Section 415(b)(5) of the FD&C Act requires that FDA issue regulations to implement section 415(b) of the FD&C Act. However, food facilities became subject to the requirements of section 415(b) of the FD&C Act, including the suspension of registration provisions, on July 3, 2011 (180 days after the date of enactment of FSMA).

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