

Regulatory Services News

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

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Director's Digest- Fall, 2014

As covered in the last issue, Regulatory Services at UK began in 1886 with the passage of a law to regulate the sale of fertilizer in the Commonwealth. This remained the sole responsibility until 1897. Over the next 12 years, ten new regulatory laws, or revisions of laws, were passed, which expanded the responsibilities of the Experiment Station to include inspection and control work of horticultural nurseries, agricultural seeds, livestock feeds, human food, medicines, and drugs. With this increased work load, the staff of Regulatory Services expanded and by 1909, nineteen of thirty two experiment station workers were engaged in regulatory work.

Although not part of our responsibilities now, a law passed in 1898 moved Regulatory Services into the arena of regulating manufacturers, merchants, and consumers of food in the state. It's hard to imagine now, but at the end of the nineteenth century the amount of adulteration and fraudulence in the food industry was very expansive. In an investigation before the U.S. Senate Committee on Pure Foods it was shown that nearly 90 percent of all food products in the country were being adulterated or misbranded in one manner or another. Until the passage of this law, Kentucky did not have a pure food law as many other states did and became a dumping ground for inferior food products that could not be sold elsewhere.

Under the new law, anyone selling food as pure or unadulterated, but which in fact was adulterated or misbranded, was subject to a fine or imprisonment. The term food included "every article used for food or drink by man, horses or cattle, except spirituous, vinous or malt liquors." The Experiment Station was authorized to establish standards of purity or strength when such standards were not fixed by statute. Foods suspected of being adulterated or misbranded were to be analyzed by the Station. When violations were found, they were to be reported to a grand jury or prosecuting attorney in the district where the food was found.

This law was not without critics as some argued that it invaded the rights of merchants and manufacturers, discriminating against certain food products which were themselves wholesome. In answer to criticisms, Director Scovell wrote to the editor of the *Louisville Courier-Journal* that "nobody objects to these articles (wholesome foods but not correctly labeled) being sold but let them be sold for what they are." Scovell offered

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examples of foods being misbranded including vinegar made from corn and colored with burnt sugar for as little as two cents a gallon but sold in Kentucky as pure cider vinegar; maple syrup being largely adulterated with glucose and sold as pure maple syrup; oleomargarine sold in Louisville as pure butter; wheat flour being adulterated with as much as 25 percent corn meal. In arguing for passage of the bill, Scovell stated: "As you will see, the bill before you does not prohibit the sale of such articles mentioned above, but compels the parties manufacturing and selling them to truly brand them in order that the purchaser may know just what he is buying."

Enforcement of the food law was hampered by a lack of funds but the work continued. Particular attention was given to milk and dairy cow housing. Of 150 milk samples examined, 35 were found adulterated. Twenty-two contained preservatives to delay souring, eight were artificially colored and nine contained skim milk or were watered down. The preservatives used were borate and formaldehyde of which the Station commented: "It is clearly a violation of the law to add preservatives to milk for the purpose of keeping it from souring, as such preservatives, at least, retard digestion when the milk is taken into the stomach, if they do not have a direct injurious effect on the system. When we remember that such milk is often sold to be fed to small children and infants, their use become criminal."

In 1898, 239 food samples were taken of which about half were adulterated. In 1899, 488 samples were taken and about one-third were adulterated. Prosecutions were forthcoming but limited because when the cases came up it was necessary for both the inspector who bought the samples and the chemist who analyzed them to appear as witnesses with no provisions to pay for their travel. Travel was not feasible and many cases were not pursued when samples were taken far from Lexington. In 1900 and again in 1904, the food law was revised to tighten the provisions regarding labeling and preservatives. Additional funding was provided to continue the work and it became possible for more cases to be brought for trial by permitting affidavits of the director to substitute for actual appearance of inspectors and chemists as witnesses.

After just four years of work and several successful prosecutions it became apparent that the Division was serious. In 1902, 210 violations were reported to county attorneys across the state but it became the policy of the Station to not prosecute if it could be avoided. Instead they would notify the manufacturers as soon as their products were found to be adulterated and in most cases the manufacturers would send a representative to discuss the matter and seek advice on how the label should be printed. Many out-of-state manufacturers opted to withdraw their objectionable food products from Kentucky distribution.

This work was clearly important in improving the quality of human food in the Commonwealth and thus the longevity of its citizens. Enlargement of the regulatory staff for fertilizer and food control plus expansion of the research program soon put a strain upon the office and laboratory facilities of the Experiment Station building which was erected in 1889 and shared with other departments of the college. Planning commenced for a new building and on February 1, 1905 the staff moved into a new building on South Limestone that is recognizable for the four columned portico extending over the front entrance. This building is now the west wing of Scovell hall and is still in use.

The Experiment Station and its staff continued to concentrate on human food in the early 1900's, paying special attention to meat and dairy products. Director Scovell and Robert Allen (chair of the Division of Food Control in the Experiment Station) were tireless crusaders for a federal pure food law which was finally attained in 1906. In 1908, the Kentucky pure food law was further revised to bring under control medicines

Continued on next page

and drugs as well as all “food and drink for man or domestic animals, including all liquors.” To provide for an expanded program of pure food work, the act allowed for expenses in administering the law to increase from \$10,500 per year to \$30,000. Food and drug work moved forward rapidly and in 1909 analyses were run on 1,500 samples of foods and beverages and 1,106 samples of drugs.

One particular incident during this period pointed out the creativity of Kentuckians. In the realm of disputed food nomenclature a question that aroused considerable national attention was the definition of “whisky.” For years a running battle had existed between the distillers of straight whiskey (aged in charred oaken barrels for at least four years) and producers of another product called whisky which consisted of ethyl alcohol or neutral spirits diluted with water, flavored with an essence and colored with burnt sugar. When the National Pure Food Law enacted in 1906 was before Congress, Representative A. O. Stanley of Kentucky, who later became governor, gave a dramatic demonstration of how this so called “whisky” was made. Standing in the forum of the house he took a vial filled with colorless neutral spirits and added some essence of rye and bourbon plus some coloring material and created what appeared to be straight whiskey. This, he said “is the kind of so-called whisky which the Pure Food bill aims to stop. It is this sort, made out of this new alcohol, that will eat the very vitals out of a coyote; it will make a howling dervish out of an anchorite; it will make a rabbit walk right up and spit in a bulldog’s eye.” The demonstration was very well received.

As mentioned earlier, the food law passed in 1898 also covered food consumed by “horses or cattle.” Understandably, early work centered on human food and regulatory work in livestock and pet food was somewhat put on the back burner. In future issues we will look at how the regulation of human food and medicine was moved away from the Experiment Station and increased duties were assigned in regards to agricultural commodities.

Darrell Johnson, Director

History is from “The College of Agriculture of the University of Kentucky” by J. Allan Smith

PERSONNEL CHANGES



Karen Cosgrove began working in the seed lab as a research analyst (germination) on July 28. She replaces Sarah Cprek who took another job within UK. Karen had worked as a Lab Technician Senior in the Soils Lab since June of last year. This is another homecoming as Karen worked in the seed lab previously as a student and temporary worker. Karen went to high school in Jessamine County and attended Bluegrass Community College, UK and Spencerian College. She lives in Lexington with her husband Matthew who works in the college of Business and Economics.



Jonathan Collett started working in the seed lab as a research analyst (purity) on June 29. He replaced the retiring Kent Von Lanken. Jonathan had worked as a Lab Technician Senior in the Feed/Fertilizer Lab since last July. This is somewhat of a homecoming for Jonathan as he worked in the seed lab while a student at UK. He has a BS degree in Forestry and worked in the forestry industry prior to his return to Regulatory Services in July of last year. Jonathan will also be taking a course in Feed Microscopy and assist with that as needed. Jonathan is from Garrard County and currently lives in Richmond.

Noxious Weed Seed Update – Stephen McMurry

When shipping seed across state lines, you should be aware of the noxious weeds in other states. The USDA list of noxious weeds has been updated for 2014. It is available online at: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5090172>.

State Noxious-Weed Seed Requirements Recognized in the Administration of the Federal Seed Act lists noxious weed seed by state and also by common and scientific names of each seed kind. No changes have been made to KY's list. Kentucky Seed Law and Regulations recognizes five prohibited noxious weeds and eight restricted noxious weeds. Restricted weeds have an allowable number per pound of seed, prohibited weeds cannot be present and have no allowance. The allowances for restricted weeds are listed in regulation can be found online at: <http://www.lrc.state.ky.us/kar/012/001/120.htm>.

Kentucky Noxious Weed Seeds

Common name (Scientific name)

Prohibited

- Balloonvine (*Cardiospermum halicacabum*)
- Canada thistle (*Cirsium arvense*)
- Johnsongrass (*Sorghum halepense*) and *S. x alnum*
- Purple moonflower (*Ipomea turbinata*)
- Quackgrass (*Agropyron repens* = *Elytrigia repens*)

Restricted

- Annual bluegrass (*Poa annua*)
- Buckhorn plantain (*Plantago lanceolata*)
- Corncockle (*Agrostemma githago*)
- Dodder (*Cuscutaspp.*)
- Giant foxtail (*Setaria faberi*)
- Ox-eye daisy (*Chrysanthemum leucanthemum* = *Luecanthemum vulgare*)
- Sorrel (*Rumex acetosella*)
- Wild onion/wild garlic (*Allium spp.*)

INSPECTOR UPDATE - JIM TRUE, INSPECTOR COORDINATOR

ASFFPCO MEETING: June 18-20 the field inspectors attended the Association of Southern Feed, Fertilizer and Pesticide Control Officials annual meeting in Montgomery, Alabama. This meeting provides valuable training for the inspectors on current feed and fertilizer topics.

The new Food Safety Modernization Act (FSMA) is currently in the process of being drafted and will have an impact on the Kentucky Feed Industry and the way we regulate the feed sampling and inspection program at the Division of Regulatory Services.

One of the new programs from FDA is the Animal Feed Regulatory Program Standards. There are 11 feed standards. Number two deals with the training for the inspectors.

During the meeting there were several presentations which will benefit the work the inspectors do during the visits and inspections to Kentucky Feed Mills. Shannon Jordre from FDA gave a presentation on Medicated Feed Mill Inspections and the current good manufacturing procedures that are required as a part of making medicated feed. This is going to become a more important part of the inspections that we conduct because of FSMA and your inspectors will be working with your feed mill to make sure you are meeting the requirements being implemented under FSMA.

There were some other presentations that discussed the other changes that will be taking place due to FSMA with the requirements for each feed mill to have a Feed Preventive Control plan implemented to monitor the production and manufacturing of medicated feeds.

FDA and the animal drug manufacturers are currently changing the availability of antibiotics used in the feed industry for growth and performance of animals. These medications are going to be limited to treating and prevention of animal sickness or prevention and no longer be available without a veterinarian's prescription. Chris Bishop from the Alabama Department of Agriculture and Inspection gave a presentation on the changes that will be taking place with the new Veterinary Feed Directives that will be phased in over the next 3 years.

SUMMER INSPECTOR MEETING: July 8-10 the staff at the Division of Regulatory Services met with the field inspectors for our annual summer meeting at Barren River State Park. We spent the 3 days discussing the sampling and inspection program for feed, seed, fertilizer and milk programs. Each program coordinator spent time reviewing the past year, discussing issues related to sampling, and setting the plan of work for each program for the next year.

FDA representatives attended the meeting and spent Wednesday morning reviewing the BSE feed mill inspections, and the licensed medicated feed mill inspections. Our inspectors have been doing these 2 both types of these inspections for several years. All 8 field inspectors and I have our FDA credentials to conduct these inspections under contract with FDA. In 2013 FDA added a new inspection to the contract for feed mills and our staff is now conducting a cGMP- current Good Manufacturing Practices- to the non-licensed medicated feed mills in Kentucky when we do the BSE inspection. If you are manufacturing any medicated feed this will be a new inspection for your facility and will be added when your inspector does your next BSE inspection. If you have any questions please ask your field inspector and he will be glad to assist you leading up to this inspection.

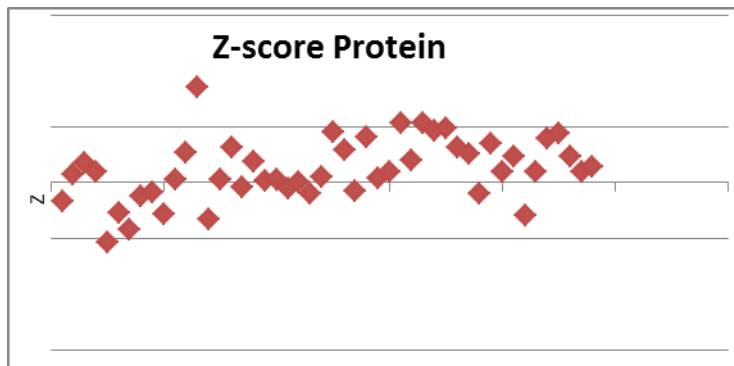
SPECIALITY PRODUCT SAMPLING: There are approximately 500 pet food and specialty manufacturing companies selling products in Kentucky. These companies have a total of over 12,000 specialty feed

products registered in the state with the Division of Regulatory Services. The field staff have completed the sampling and registration work for these products in June and July. These products included dry dog and cat food and treats, other small pet products, deer, and equine products. The inspectors sample products from every company that is in distribution in the state. They determine the number of samples to collect based on how many products a company has registered. During the last two months the inspectors have sampled just over 700 specialty products.

What Does Quality Mean At Regulatory Services? - Sharon F. Webb, Ph.D., Director, Quality Control

Quality can mean different things for different people. For us at Regulatory Services, it means that all steps of processing samples—from the time an inspector takes it, until the analytical results are reported out to the dealers, manufacturers, and farmers—follow certain procedures so that the analytical values found are unbiased and accurate. There are several tools in our toolbox to make sure that this happens. One of the tools is using validated methods to take, split, and analyze the samples. Some may wonder what is so important to use “validated” methods. It is important to use such methods because they are typically the final version that many laboratories used in what is called a collaborative study. In a collaborative study, a large number of laboratories use the same method to analyze a certain property (e.g. protein, calcium, fiber, etc.) in many different types of samples (e.g. poultry feed, premix, dry dog food, etc.). The results then undergo strict statistical analysis protocol to determine if the method is the correct one for the specific property for the specific sample type. Our inspectors follow validated methods when taking feed and fertilizer samples. And once the sample arrives at the laboratory, validated methods are used in splitting, grinding, digesting, extracting, and analyzing the property of the sample. This is only the first step of ensuring that the analytical result is unbiased and accurate.

So, we have taken the sample correctly and are using a validated method when analyzing the sample, how do we know that our results are unbiased and accurate? In order to monitor our laboratory performance, we participate in proficiency testing programs. There is one main program for feed and feed ingredients with 2 additional add-on programs and there are 4 programs that utilize fertilizer and fertilizer ingredients that we participate in. Once we have analyzed the properties of the sample from the program, we report the answers and the methods that we used. All results that are reported by all the participants in the programs are statistically analyzed. Once the math has been performed, we can then compare our value to the participants’ average, called the consensus value, by using the all of the participants’ standard deviation. It sounds complicated, and the statistics involved are, but by charting our results based on the consensus value and method standard deviation, we can easily evaluate our lab performance. This chart is called a control chart and it is monitored to look for trends so that bias and accuracy can be observed. Let’s look at the chart below.



Continued next page

This is our charted results for a common property of feed, protein, over a span of 4 years. It is a good example of our laboratory performance because it shows that our results as compared to the rest of the participants' performance for protein are very tightly centered on the consensus value with no apparent bias. Each property that we analyze has its own chart that is monitored and evaluated. So, now we have two tools in our tool box monitoring the quality in our laboratory results. What's next?

Another valuable tool we use to ensure quality results is by including quality check samples in each set of analysis. Let's think about a mineral premix. In a mineral premix certain minerals are guaranteed to be present in certain concentrations. If we want to make sure that when we analyze this sample that we have a high degree of accuracy and no bias, we will include quality check samples that have the minerals present near to the guarantees of the minerals in the sample. This quality check sample will be treated as a regular sample as it will be weighed out, digested, and analyzed in the same way as regular samples. An example of a quality check sample is a proficiency sample from one of the programs we participate in or perhaps a reference material from another known and reliable source such as the National Institute of Standards and Technology. The results from each time it is analyzed is compared to its consensus or certified value and monitored to make sure that each set of samples were digested and analyzed both accurately and unbiased. Another type of quality check is our instrument calibration verification checks. We analyze all of our minerals via ICP-OES (Inductively Coupled Plasma-Optical Emission Spectroscopy) which means we are measuring the strength of each mineral at certain wavelengths. How do we know that each wavelength is calibrated correctly? We use a purchased standard that contains all of the minerals and are certified to be present at a certain concentration within a certain precision. This is monitored over time as well to ensure accurate and unbiased analytical results.

By using validated methods, participating in proficiency check sample programs, and by including quality reference materials in our analyses, we monitor the precision, accuracy, and bias of each analyte. This makes sure that when we report analytical values for an Official Feed or Fertilizer Sample that has been taken by one of our highly trained inspectors, that our findings are accurate and unbiased. We are continually looking for ways to improve our quality standards. This is why we are heavily involved in organizations at the regional, state, national, and in some cases international levels. It is important to keep on top of new strategies of collecting and analyzing samples. We take a leadership role at the national level so that quality standards are upheld and improved upon. We will continue to improve so that our consumers, stakeholders, and farmers are protected. We currently follow the Association of American Feed Control Officials' Quality Assurance/Quality Control Guidelines for State Feed Laboratories 2007 and will be improving upon these standards.

Feed Mill Inspections-G. Alan Harrison, Coordinator Feed/Milk Programs

Along with the collection of samples, the inspection function of the Feed Division of Regulatory Services is one of the more visible duties of our inspection staff. Inspections are conducted under the authority of KRS 250.581. This statute states that our inspectors may inspect (during normal business hours) any factory, warehouse, or establishment within the state in which commercial feeds are manufactured, processed, packed, or held for distribution. Inspectors are required to present appropriate credentials and provide a written notice to the person in charge.

For several years, our inspection program has been tied to our working partnership with the Food & Drug

Administration (FDA). Regulatory Services and FDA have an agreement for a set number of inspections to be conducted at Kentucky facilities each year. Basically, the type of inspection depends on the facility and the products they produce or distribute. One important aspect of our inspection partnership with FDA is that this allows the majority of Kentucky manufacturers to be inspected by their state rather than federal officials. BSE Rule inspections are conducted at both feed manufacturers and dealers. These inspections assure that mills are following FDA guidelines and are in compliance with rules prohibiting the use of ruminant proteins in feeds intended for other ruminant animals. These rules are in place to prevent the establishment and spread of bovine spongiform encephalopathy (BSE). Feed mills receiving prohibited animal protein materials must follow adequate procedures to prevent any chance of those materials getting into feeds for ruminants.

Good Manufacturing Practice (GMP) inspections are conducted at feed manufacturers involved in the production of medicated animal feed. The purpose of these inspections is to ensure several safe feed practices are followed: (1) approved drug levels are used, (2) proper mixing procedures are followed, (3) feed ingredients are monitored, (4) good record keeping is followed, (5) good housekeeping protocols are followed, and (6) a recall plan is in place. Mills making medicated feeds fall into two categories: those using more concentrated drugs and required to obtain a license from FDA and those using more diluted drugs and not requiring an FDA license. Currently, there are 8 feed mills in Kentucky that require an FDA license to produce medicated feed and approximately 60 manufacturers considered non-licensed medicated mills.

Licensed mills are inspected every 2 years or less and these manufacturers are quite familiar with the inspection process. GMP inspections have been conducted at some Kentucky non-licensed medicated mills in the past, but our division is now making a strong effort to inspect each of these mills every 2-3 years. We inspected 18 non-licensed medicated mills last year and expect to visit another 24 in the next 12 months. The inspections are somewhat less detailed than those conducted at the licensed mills, but do focus on proper manufacturing and labeling of medicated feed. Our inspectors are always available to answer any questions manufacturers may have regarding good manufacturing practices.

The ultimate goal of our inspection program is assure that all feed produced meets intended guarantees and is not adulterated. This is especially critical with medicated feed which must contain only drugs approved for the intended purpose, the proper species, and the appropriate level. All of us associated with animal agriculture must work together to avoid risks to public and animal health and the potential loss of consumer confidence in our food supply.

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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Fertilizer Official Sample Record- Stephen McMurry

July 1, 2013 thru June 30, 2014

The analysis of fertilizers for the fiscal year 2013 thru 2014 is now complete. The sample record of registrants and licensees was sent out a few weeks ago. These results will be published in our annual regulatory bulletin in the next few months. Please review these records and report any discrepancies to our office as soon as possible.

Highlights of this past year are below:

| | |
|---|--------|
| Overall deficiency rate of all Official Samples | 7% |
| Bagged samples deficiency rate | 15% |
| Bulk sample deficiency rate | 5% |
| Total tons sampled | 51,300 |

| Form | Type | Number of Samples | Samples of Total % | Tons Sampled | Tons Sampled of Total % | Sample Deficiency Rate % |
|--------|---------------|-------------------|--------------------|--------------|-------------------------|--------------------------|
| Bag | Blended Grade | 286 | 11 | 1,334 | 3 | 16 |
| Bag | Manufactured | 99 | 4 | 580 | 1 | 13 |
| Bag | Material | 9 | 0 | 81 | 0 | 11 |
| Bag | Custom Mix | 2 | 0 | 18 | 0 | 0 |
| | | | | | | |
| Bulk | Manufactured | 4 | 0 | 105 | 0 | 0 |
| Bulk | Material | 874 | 32 | 40,553 | 79 | 1 |
| Bulk | Custom Mix | 1,292 | 48 | 5,917 | 12 | 8 |
| | | | | | | |
| Liquid | Blended Grade | 82 | 3 | 1,546 | 3 | 10 |
| Liquid | Manufactured | 18 | 1 | 26 | 0 | 11 |
| Liquid | Material | 28 | 1 | 967 | 2 | 4 |
| Liquid | Custom Mix | 8 | 0 | 173 | 0 | 63 |

Bioterrorism Act Biennial Registration- As taken from the FDA website.

Domestic and foreign facilities that manufacture, process, pack, or hold food, as defined in the Food, Drug and Cosmetic Act, for human or animal consumption in the U.S. must register with FDA.

During the period beginning on October 1 and ending on December 31 of each even-numbered year, a registrant that has submitted a registration under paragraph (1) shall submit to the FDA a renewal registration containing the information described in paragraph (2). The FDA shall provide for an abbreviated registration renewal process for any registrant that has not had any changes to such information since the registrant submitted the preceding registration or registration renewal for the facility involved.

This may be done electronic by going to: www.access.fda.gov .

Food Facility Registration User Guide: Biennial Registration Renewal

Once you are logged in to FDA Industry Systems choose "Food Facility Registration" from the list of systems available. From the Main Menu in the Food Facility Registration Module (FFRM) Home (Figure 1) choose "Biennial Registration Renewal."

Figure 1:



The system will display a list of all registrations that are available for the biennial registration. Select the registration; the system will display a review screen (figure 2).

Figure 2:

The screenshot shows a registration review screen. At the top, it says "Please review your registration. If all information is correct, click the Submit button below. To make changes to a section, click the Edit button for that section." Below this, there is a date and time stamp: "Date: 09/26/2012 11:09:02". The form is divided into three sections, each with an "Edit" button. Section 1 is "TYPE OF REGISTRATION" with a dropdown menu set to "DOMESTIC REGISTRATION" and a "Yes/No" question: "ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY?". Section 2 is "FACILITY NAME / ADDRESS INFORMATION" with fields for Facility Name, Street Address, City, State, ZIP Code, and Phone Number. Section 3 is "PREFERRED MAILING ADDRESS INFORMATION (Optional)" with a checkbox for "If information is the same as section 2, check the box:" and fields for Name, Address, City, State, ZIP Code, and Phone Number.

Only the sections of your registration with an "Edit" button next to it may be updated during the biennial registration renewal.

Once you have reviewed the information and made updates where necessary, choose to Submit Biennial Registration Renewal.

If you do not wish to submit your biennial registration renewal at this time, select the Cancel option.

Your food facility registration has been renewed.

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RETURN SERVICE REQUESTED

