



# OTSC Quarterly Newsletter



Volume 21, No. 3

Office of the Texas State Chemist

August 2014

## Regulatory Science Graduates

Congratulations to Paulette Bunyapanasarn, Dr. Susie Dai & Ben Jones, who have successfully completed the coursework needed to earn the Regulatory Science in Food Systems Graduate Certificate. Since the inception of the Regulatory Science Graduate Program in 2012, approximately 90 students have registered in 13 course offerings. During the same period, lab professionals from 35 countries around the world have participated in the Laboratory Quality Systems course as part of our cooperation with the Food and Agriculture Organization (FAO). Last Spring, a new graduate course in Regulatory Science Methodology was offered. This course focused on the practical knowledge needed to achieve regulatory compliance and evaluate the effectiveness of regulatory agencies and industry. According to comments from past Regulatory Science Graduate Program participants, they have been able to successfully incorporate the knowledge gained in these courses into their professional projects. Michael Lennox, the program's first graduate certificate recipient, credits the program for helping him under-

stand how "activities I do in the normal course of business have given me cause to reflect, **now knowing why they are done that way**, not just that they are." In the future, the graduate program will be expanded to offer an interdisciplinary Masters of Science Degree in Regulatory Science. For more information on the Regulatory Science Graduate Program, please contact Prabha Vasudevan ([prabha@otsc.tamu.edu](mailto:prabha@otsc.tamu.edu)).



Regulatory Science in Food Systems Graduate Certificate recipients: Pictured from left Mr. Benjamin Jones, Ms. Paulette Bunyapanasarn and Dr. Susie Dai with program director, Dr. Tim Herrman.

Regulatory Science in Food Systems Online Course Offerings	
Fall (August – December)	Spring (January – May)
<u>SCSC 634</u> Regulatory Science: Principles & Practices in Food Systems (3 SCH)	<u>SCSC 636</u> Regulatory Science Methodology in Food Systems (3 SCH)
<u>SCSC 635 / AGECE 639</u> Comparative Global Standards in Food Systems (3 SCH)	<u>AGECE 638</u> Managerial Economics for Regulatory Science (3 SCH)
<u>SCSC 629 / VTMI 629</u> Laboratory Quality Systems (3 SCH)	<u>SCSC 629 / VTMI 629</u> Laboratory Quality Systems (3 SCH)

## FSMA Update

It has been over 3.5 years since the Food Safety Modernization Act was signed into law. It has five main themes: partnership, prevention, inspection/compliance, response, imports and training. One of the principles of the FSMA is that it should be a complex system that accommodates both human and animal food. It should build on past progresses, such as HACCP, and identify gaps. There should be sufficient outreach to build on the existing structure without duplicating existing programs; plus training and technical assistance to deal with gaps. These were important goals but lacking a critical ingredient. If industry had to change, it followed that FDA would have to change with it. For example, voluntary compliance is more desirable than gathering evidence for a legal case. If voluntary compliance is not achieved, new enforcement rules will be used, such as mandatory recalls. To date, FDA has declared Phase I to be nearing completion. Six core teams drafted standards for preventive controls, inspection/compliance, imports, federal/state integration, fees and reports. Phase II is an extension of Phase I with the continuation of rulemaking and guidance. In Phase II, implementation of the final rules with progress established through guidance and other outreach activities is the main goal. Phase III of the FSMA will be a workgroup change from drafting rules to teams working on education and outreach, training regulators, data and IT management, performance goals

## Developing a National Recall Program

In October, 2012, OTSC was awarded a grant to facilitate long-term improvement to the national food safety system by building the capacity and capability of food safety entities to take appropriate action, including planning and preparing to implement product recall in response to a food safety event. This project involves 4 major initiatives:

- Conducting a gap analysis of the recall system in the U.S., the Caribbean and Latin American countries
- Development of a Recall Best Practice Manual
- Creation and delivery of online graduate and continuing education training on Recall Best Practices
- Development of a web-based recall information sharing/reporting system.

(metrics) and inspections to measure compliance based on new metrics. Therefore, FDA is attempting to meet the challenges and change along with industry.

FDA will undergo a radical culture change. The emphasis will be on its public health role, first, and its regulatory role, second. FDA will have to educate other regulatory agencies, industry and the consumer in order to accomplish this change. Another major policy shift is that FDA will have to learn from the company's food safety culture to effectively change FDA's culture. Other changes that are necessary to make the new approaches work are: continue to engage stakeholders by speaking as one voice; to a greater degree integrate inspection and compliance staff; invest in regular training to promote consistent inspections and decision making; provide real time resources during inspections; develop robust data integration and analysis for information sharing; incorporate public health metrics instead of widget counting, such as the number of inspections; and work closely with regulatory counterparts at the state level. Lastly, FDA will be educating before and after they regulate. This will facilitate industry's implementation of modern preventive practices where high risk firms are inspected more frequently. Each firm's food safety approach will be recognized because one size does not fit for all, especially with a wider range and number of inspections. FDA will not be able to perform the task alone.

In Spring 2014, a recall training component was delivered as part of the Regulatory Science Methodology in Food Systems graduate course. As part of this course, a checklist was developed to identify gaps and assess the current status of various national recall systems. To help countries in Latin America and the Caribbean address gaps in their national recall systems, a Best Practices for Recall Manual was developed in both English and Spanish. The main purpose of this manual is to assist developing countries in building an effective and efficient recall system. The first draft of this manual will be presented for review at Codex Committee for Latin American and Caribbean countries later this year. Based on comments from members of the Codex committee, a final version of the manual will be published in 2015.

## New Laboratory Instrument Acquisition - UHPLC

A new ultra high pressure liquid chromatography (UHPLC) instrument was added in Office of the Texas State Chemist (OTSC) to augment the current capacity of the Agriculture Analytical Service (AAS). A method for analyzing aflatoxin has been validated on the new instrument to prepare for the 2014 corn harvest. Compared to the old HPLC method, the new method shortened the analysis time to one third, reduced the chemical consumption three fold thus providing a more efficient and economical analysis. The UHPLC will allow the lab to further increase analytical capacity and capability.



## International Journal of Regulatory Science

Advancing the science of creating tools, standards and practices to improve the protection and compliance of food systems is the focus of a new graduate curriculum and journal focusing on regulatory science. The second volume of the IJRS focuses on the role of standardization in regulatory science.

Regulators and industry use standards to achieve uniformity in the feed and food industry and provide a tool to measure conformance. Often standards are inculcated into regulations. As the food and feed industry pursues implementation of the Food Safety Modernization Act, a parallel activity is underway within the regulatory community involving the pursuit of standardization. The Animal Feed Regulatory Program Standard, issued in 2014, represents the third in a suite of standards designed to achieve reproducibility within and between regulatory agencies. The other two standards for regulatory bodies are the Manufactured Food Regulatory Program Standard and the Voluntary Retail Food Establishment Regulatory Program Standard.

The second volume of IJRS includes articles on the adoption of standards for laboratories, standardization of aflatoxin measurement in the grain industry, and development of best recall practices. The journal augments a graduate certificate program in Regulatory Science offered by Texas A&M, the journal is open access, and authors incur no publication costs. A first of its kind, peer reviewed online journal is accessible at <https://journals.tdl.org/intlregsci/index.php/intlregsci/index>.



## Aflatoxin Kits Evaluation for One Sample Strategy

Since 2010, Office of the Texas State Chemist has been evaluating aflatoxin testing kit performance to assist the industry to improve analytical measurement capability. In 2011, OTSC launched the "One Sample Strategy" aflatoxin risk management program to address the variability in aflatoxin measurement. OTSC continues to test and evaluate commercial aflatoxin testing kits that are currently in the market to ensure their fitness for purpose. In 2014, additional aflatoxin testing kits were evaluated within the Agriculture Analytical Service at OTSC, including Charm WET XR and Neogen Q+ Green. These kits utilize water based extraction in place of organic solvents. The evaluation results are available to the public upon request.



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*Protects consumers & enhances Agri-Business through its Feed & Fertilizer Regulatory Compliance Program, surveillance & monitoring of Animal-Human health & environmental hazards, & preparedness planning.*

## Introducing Feed & Fertilizer Inspectors

**Ethan Stuckly**  
**Feed & Fertilizer Inspector**  
**Area 17**



Hi my name is Ethan Stuckly. I was born and raised in a little town called Pilot Point, TX where I was the middle of 3 boys. I graduated high school in 2008, then I attended Tarleton State University. I played baseball at Tarleton for 4 years and also received a Bachelor of Science degree. Agri-

culture played a big part in making me who am I today. Showing cattle and pigs and many other things have taught me responsibility and discipline. I always wanted to do something to help affect the Agricultural Industry and I believe working with the Office of the Texas State Chemist can help me achieve my goal in life.

**Frank Royal**  
**Feed & Fertilizer Inspector**  
**Area 18**



I have spent all of my life being involved with agriculture. I was raised working on the family cattle ranch in South Texas and throughout school and college worked on several ranches in West Texas, built fence, drove a feed truck and worked as a pen rider. I spent several years in North Texas working in the farming industry mainly with milo and cotton before returning to school and getting a degree from Lubbock Christian University. For the past ten plus years I worked for an agricultural cooperative in East Central Texas, first as a field representative, then later as the petroleum division manager. My varied experience in agriculture has given me the skills and knowledge that I look forward to utilizing while working for the Office of the Texas State Chemist as a Feed and Fertilizer Inspector.