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*Editorial*

## **Standardization and the Role of Regulatory Science**

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*Advancing the science of creating tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products*, a working definition for Regulatory Science by the Food and Drug Administration (FDA), aligns closely with the Food Safety Modernization Act (FSMA). Intertwined within this definition and implicit within FSMA is a focus on standardization for industry and regulatory agencies alike. As food establishments seek to conform to regulatory requirements within this Act, a parallel activity is underway within the regulatory community involving standardization.

The Animal Feed Regulatory Program Standards (AFRPS), released January 2014, represents the third in a suite of standards designed to achieve consistency, uniformity and reproducibility within and between regulatory agencies. The Manufactured Food Regulatory Program Standards and the Voluntary National Retail Food Regulatory Program Standards were published in September 2010 and January 2013, respectively. These three standards are partially a result of the 2008 Partnership for Food Protection (PFP) meeting between food safety regulatory authorities, which was held in St. Louis, MO. Since 2008, representatives from federal, state and local regulatory agencies have worked in teams to develop best practices for regulatory professionals that maximize resource efficiency in the pursuit of an Integrated Food Safety System (IFSS). As highlighted in the background to the AFRPS, “One of the foundational principles of an IFSS is the implementation and uniform application of model standards so that Federal, State, territorial, tribal, and local regulatory agencies conduct inspections under the same set of standards.” Arguably, FSMA formalized the efforts of the PFP and IFSS by requiring establishment of a network of laboratories (Section 418 of the Food Drug and Cosmetic Act ) and mandated allocation of resources to regulatory agencies that partner with FDA during the implementation of FSMA (Section 419 of the Food Drug and Cosmetic Act).

A report by the National Research Council committee, which investigated the federal oversight of food safety including the 2007 Food Protection Plan – a precursor to the FSMA, highlighted the hurdles the FDA and their state counterparts must overcome to achieve standardization. The committee observed, with regard to the FDA Investigations Operations Manual, that it “has not been reviewed externally to determine, for example, whether it is up to date, overly prescriptive, or otherwise less than ideal.” Similarly, most state regulatory agencies’ operation manuals follow a model developed by their respective associations and lack external peer review. Regulatory associations and their members’ pursuit of conformance to new regulatory program standards will necessitate a systems approach that includes mapping the flow of their regulatory processes, developing standard operating procedures and implementing a continuous

improvement cycle. For regulatory agencies, a systems approach will involve combining the development of a statistically derived risk-based plan of work with field sampling, investigation activities, and laboratory operations into a seamless regulatory process within and between agencies.

Standardization encompasses the goals outlined in Codex Alimentarius to achieve harmonization and equivalency. Among the purposes of Codex Alimentarius is to establish definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade. Equivalence is the state wherein different measures applied by an exporting country, though different than those measures applied by the importing country, achieve, as demonstrated by the exporting country, the importing country's appropriate level of protection. A tangential movement is underway within industry to achieve standardization among the myriad of certification schemes developed by respective associations or their consumers in different regions of the world. Drivers for these certification schemes are similar to those within Codex and the regulatory program standards and include confidence among consumers that the product is safe and facilitation of global trade. Standardization will yield a similar outcome among regulatory risk managers and industry.

This issue of JRS includes an article on progress by state food laboratories to achieve ISO 17025:2005 accreditation in a program funded by FDA towards building a laboratory network. The capability of a laboratory to produce accurate and reproducible results is foundational to successful laboratory operations, data reliability, and, ultimately, regulatory risk management. An article on co-regulation of aflatoxin risk management contained in this issue of JRS highlights the need for standardization between state and federal regulatory agencies and grain elevators to achieve uniform procedures and results. The One Sample Strategy program described in the article "Aflatoxin Sampling and Testing Proficiency in the Texas Grain Industry" captures the concept of co-regulation, where an activity correctly performed will yield results that are shared amongst all who manage the risk associated with aflatoxin contaminated grain including the firm and regulatory agencies. Another article in this issue considers the development of standardized best recall practices among competent food safety authorities.

The articles in this issue that consider standardization represent a small fraction of the global activities involving this important topic. It is a goal of the JRS to provide a platform for all who are pursuing standardization within the scope of regulatory science to share their progress in this peer reviewed electronic publication at no cost to the reader and author.