Journal of Extension
www.joe.org

April 2017
Volume 55
Number 2
Article # 2COM1
Commentary

The Need for Evidence-Based Outreach in the Current Food Safety Regulatory Landscape

Abstract

As the most comprehensive legislation related to safety of U.S. agricultural production and food manufacturing in more than 70 years, the Food Safety Modernization Act (FSMA) aims to ensure safety of domestic and imported foods by shifting the focus of producers, processors, and federal regulatory agencies from response to prevention. Considering the diversity of industries in need of FSMA outreach and technical assistance, land-grant institutions and Extension are presented with a challenge and historic opportunity. Systematic and evidence-based needs assessment would enable Extension educators to efficiently triage resources to assist the most vulnerable Extension stakeholders.

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Food Safety: A Moving Target

Unlike the vast majority of species, microbial communities have the ability of moving toward diversity and *fitness* through vertical and horizontal gene transfer mechanisms, enabling the "emergence" of organisms with new characteristics in response to evolving agricultural and manufacturing environments. Consequently, assuring the safety of the public against natural and anthropogenic microbial pathogens in agricultural and food commodities is a daunting task involving a moving target. Expanding global travel and commerce, increased proportions of food safety at-risk populations, and consumer demand for nontraditional commodities, such as minimally processed and ready-to-eat products, additionally foster breeding grounds for emerging, novel, and reemerging infectious diseases associated with agricultural and food commodities.

Food-borne diseases cause an estimated 420,000 deaths every year around the globe and are collectively

responsible for the loss of over 33 million years of healthy living annually (World Health Organization, 2015). Earlier estimates by the Centers for Disease Control and Prevention indicated that every year in the United States about 300,000 hospitalizations and more than 5,000 deaths were occurring due to food-borne pathogens (Mead et al., 1999). More recent epidemiological investigations have revealed similar trends, showing that roughly one out of six Americans experiences illness from these pathogens (Scallan et al., 2011).

A vast majority of the endeavors to control contamination in agricultural and food environments have been primarily reactions to food safety episodes (Hamburg, 2016), addressing an outbreak or initiating a recall after an occurrence. A rigorous, systematic, and prevention-based approach has been part of the food safety regulatory climate for only limited, high-risk sectors of manufacturing, necessitating adherence to mandatory requirements related to hazard analysis and critical control points for certain sectors of the red meat, seafood, poultry, and juice industries (Fouladkhah, 2011; Martin, Knabel, & Mendenhall, 1999).

Agricultural commodities and food manufacturing markets are highly volatile—producers' and processors' profits can be adversely affected to great extent when food safety outbreaks occur anywhere in the country. In addition to loss of productivity and consumer insecurity, the annual cost of food-borne diseases in the United States is estimated to be around $77.7 billion (Scharff, 2012). In case of negligence from a producer or processor, where the legal and medical expenses could be burdened back to the entrepreneur, costs of illness episodes could well exceed $100,000 per case (Scharff, 2012). Land-grant institutions and Extension programs play a crucial role in disseminating food safety and regulatory affairs materials and providing technical assistance to various entrepreneurs, particularly small, mid-sized, beginner, and socioeconomically disadvantaged producers and processors (Barton, & Barbeau, 1992; Fouladkhah, 2015).

Food Safety Modernization Act

Signed into law in January 2011, the Food Safety Modernization Act (FSMA) is the most comprehensive legislation related to safety of U.S. agricultural production and food manufacturing in more than 70 years. The FSMA aims to ensure safety of domestic and imported foods by shifting the focus of producers, processors, and federal regulatory agencies from response to contamination to preventive measures. The implementation of FSMA, as a comprehensive law with over 50 rules, has been in progress and has gained increasing momentum since its introduction in 2011. For the first time in the history of the country, the U.S. Food and Drug Administration (FDA) has a comprehensive legislative mandate to require prevention-based controls across a wide array of agricultural and food industries to prevent or considerably minimize the likelihood of food safety problems (Fouladkhah, 2015). Among others, some of the fundamental elements of the legislation are

- accredited third-party certification,
- foreign supplier verification programs for importers of food for humans and animals,
- mitigation strategies to protect food against intentional adulteration,
- preventive controls for food for animals,
- preventive controls for human food,
- sanitary transportation of human and animal food, and

- standards for produce safety.

The legislation sets forth imposing regulatory requirements for a wide array of agricultural production operations and manufacturing facilities handling domestic and imported products. In many cases, operations and facilities are facing daunting requirements of this sort for the first time in the histories of their corresponding industries (U.S. Food and Drug Administration [FDA], 2016).

The Challenge: Meeting the Regulatory Requirements

Although the legislation is expected to appreciably enhance the health of the public by further reducing the burden of food-borne diseases, hospitalizations, and deaths, it requires extensive actions from producers and processors in the nation and around the globe. For example, frequent surface and subsurface water testing, hazard analysis, validation of existing processes, biological soil amendment, wildlife control management planning, health and hygiene training, equipment and facilities sanitary design, record keeping, documentation, development of validated control measures, and corrective actions are some of the new requirements for many producers or processors in the FSMA era.

Large-scale producers and processors are subject to the earliest compliance dates and, thus, require accelerated support for meeting the regulatory requirements. Some very small operations—for example, farmers having average annual value of sold produce of $25,000 or less during the previous 3-year period—could currently receive exemptions from FSMA requirements. For these exempt emerging entrepreneurs, FSMA compliance information and technical assistance could help them enter larger, more profitable markets, enhancing the prospect of expanding their businesses, which otherwise would have to remain low in profit to continue to be exempt. For medium-sized nonexempt farmers and processors, the information would be critical for continued access to the market—in the FSMA era, the FDA has accelerated authority related to both mandatory recalls and suspension of noncompliant facilities (U.S. FDA, 2015a, 2015b).

Available outreach dissemination materials, such as standardized training curricula and train-the-trainer programs recognized as adequate by the FSMA regulatory authority, provide highlights and identify main requirements of the regulation for educators and practitioners. However, Extension educators and instructors bear the responsibility of development and delivery of industry-specific materials for an array of entrepreneurs in their corresponding regions.

Needs Assessment for Evidence-Based Outreach

Various sectors of agricultural production and food manufacturing are in immediate need of food safety outreach and technical assistance related to meeting the requirements of this new regulatory landscape. Producers of high-risk agricultural commodities, such as berries, small fruits, vegetables, leafy greens, ground and tree nuts, and sprouts, as well as manufacturers of various ready-to-eat products, minimally processed commodities, snacks, cereals and other grained-based products, and frozen merchandise, to name a few, will need to comply with the new regulatory requirements.

Whereas large-scale entrepreneurs might be able to afford third-party consultations or additional quality and food safety staff to help them meet the new requirements, small and medium-sized operations, which produce a considerable proportion of the country's food supply (U.S. Department of Agriculture Economic Research Service, 2016), are among the most vulnerable in the new food safety regulatory climate. Land-grant institutions and

Extension educators are now presented with a challenge and a historic opportunity to assist the plethora of producers and processors that must meet the new requirements to gain and/or maintain access to their markets.

An evidence-based needs assessment approach involving inclusion of input from target groups and practitioners appears to be an inevitable strategy for continued success of the land-grant mission. Conduct of industry-specific qualitative assessments, such as focus group interviews with various entrepreneurs (e.g., beginner businesses; small, medium, or large operations; hobbyists; entrepreneurs from various socioeconomic statuses), and successful execution of quantitative systematic needs assessments, such as the Delphi approach, could enable land-grant institutions to disseminate outreach and technical assistance materials and to conduct programs for the broad set of stakeholders facing challenges in the current regulatory landscape.

Considering the diversity of industries in need of materials and technical assistance related to FSMA compliance, systematic needs assessments, rather than traditional eminence-based approaches, will enable educators and practitioners to cost-effectively triage their resources to assist the most vulnerable Extension stakeholders. Such assessments could lead to development of high-impact, tailored FSMA outreach and technical assistance materials, ultimately further reducing the current burden of illnesses, hospitalizations, and premature deaths associated with consumption of contaminated agricultural and food commodities.

Acknowledgment

Relevant extramural funding support to the Public Health Microbiology Outreach and Research Laboratory of Tennessee State University by the U.S. Department of Agriculture National Institute of Food and Agriculture is appreciated (Award numbers: 2016-70020-25805 & 2015-70020-24397). Content of the current publication does not necessarily reflect the views of the funding agency.

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