

# Regulatory Requirements for Early-Career Labor and Emerging Entrepreneurs in the Current Food Safety Regulatory Landscape

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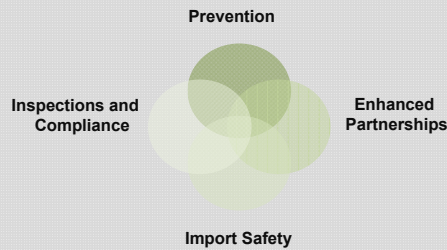
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## ABSTRACT

Food Safety Modernization Act (FSMA) is the most comprehensive legislation related to safety of U.S. food manufacturing and agricultural production in more than 70 years. 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. The legislation 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. Although FSMA is expected to appreciably enhance the health of the public by further reducing the burden of the food-borne diseases, hospitalizations, and deaths, it requires extensive steps from employees and employers in the nation. As an example, health and hygiene training for employee; training the labor for record keeping, documentation, development of validated control measures; and conduct of hazard analysis, corrective actions, validation of existing processes, and biological soil amendment are some of the new requirements for many employees and entrepreneurs for the first time in the history of each corresponding industry. This presentation discusses the overview of FSMA with particular emphasis on regulatory requirements for emerging entrepreneurs and employees in various processing and production centers, undergoing new requirements in the current food safety regulatory landscape. The information would be of particular importance for early-career labor and emerging entrepreneurs, enhancing the prospect of expanding their businesses, which otherwise would have to remain low in profit in order to stay inside the FSMA exemption "box."

## FOOD SAFETY MODERNIZATION ACT



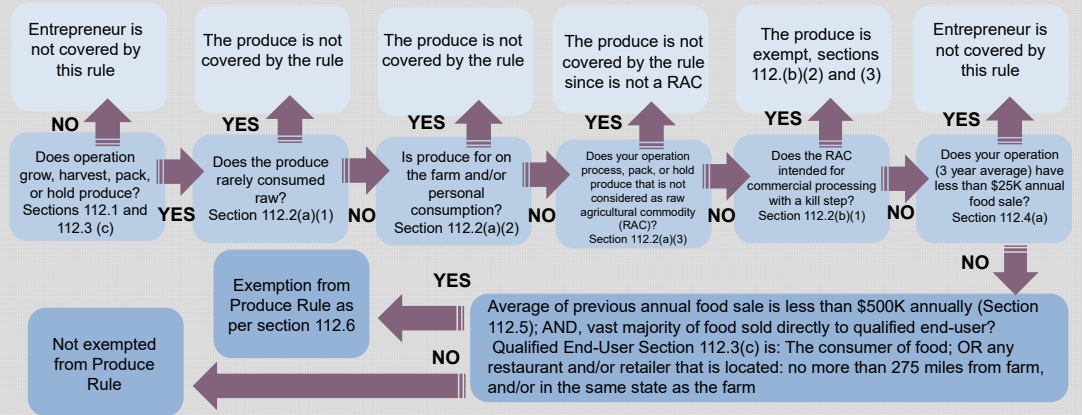
- Prevention, increase in inspection, enhanced partnership, and import safety are foundations of Food Safety Modernization Act (FDA, 2015a,b).
- Signed into law in January 2011, the Food Safety Modernization Act (FSMA) is the most comprehensive legislation related to safety of U.S. food manufacturing and agricultural production 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 history of the country, Food and Drug Administration (FDA) has a comprehensive legislative mandate to require prevention-based controls across a wide array of food and agricultural industries to prevent or considerably minimize the likelihood of food safety problems occurrence (Fouladkhal, 2015).
- Among others, some of the fundamental sections 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,
  - Standards for produce safety.

- These are imposing regulatory requirements on a wide array of domestic and imported manufacturing facilities and agricultural productions, in many cases, for the first time in the history of each corresponding industry (FDA, 2016).
- Prior to FSMA, vast majority of the endeavors to control contamination in food and agricultural environments have been primarily reactions to food safety episodes (Hamburg, 2016), addressing an outbreak or initiating a recall after an occurrence

## 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 food and agricultural commodities is a daunting task and a moving target.
- Recent Epidemiological Study:** (Scallan et al., 2011)
  - 47.8 million illnesses, 127,839 hospitalizations, and more than 3,037 deaths in the United States.
  - 9.4 million illnesses, 55,961 hospitalizations, and 1,351 deaths are caused by 31 known foodborne agents.
- Losses beyond Healthcare:** (Fouladkhal, 2017)
  - In addition to consumer insecurity, foodborne diseases cause around \$77.7 billion for losses in productivity and economical losses.
  - Approximately 30% of population are especially "at risk" for foodborne diseases
- Contributors to Foodborne Illness & Death:** (CDC, 2017)
  - Fresh produce:** 46% of illness, 23% of death
  - Meat and poultry:** 23% of illness, 29% of death
  - Dairy and eggs:** 20% of illness, 15% of death
  - Fish and shellfish:** 6.1% of illness, 6.4% of death

## EXEMPTION AND COMPLIANCE FOR FOOD SAFETY MODERNIZATION ACT PRODUCE RULE



## THE CHALLENGE: MEETING THE REGULATORY REQUIREMENT

- 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**, could currently receive exemptions from FSMA requirements. For these exempt emerging entrepreneurs, FSMA compliance information enhances the prospect of expanding their businesses, which otherwise would have to remain low in profit in order to stay inside the exemption "box."
- For **medium-sized nonexempt farmers and processors**, the information would be critical for continued access to the market- in the post-FSMA era, the Food and Drug Administration has accelerated authority related to both mandatory recalls and suspension of noncompliant facilities (FDA, 2015a; FDA 2015b).

## NEEDS ASSESSMENT FOR EVIDENCE-BASED OUTREACH

- Various sectors of food manufacturing and agricultural production are in immediate need of food safety outreach and technical assistance for meeting the requirements of this new regulatory landscape.
- 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, medium- and small-sized operations, which produce a considerable proportion of the country's food supply (USDA, 2016), are among the most vulnerable in the new food safety regulatory climate.
- 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, would enable educators and practitioners to cost-effectively triage their resources to assist the most vulnerable Extension stakeholders.
- Expanding global travel and commerce, increased proportions of food safety at-risk populations, and consumer demand for nontraditional commodities additionally foster breeding grounds for emerging infectious diseases
- 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 food and agricultural commodities

## AUTHOR & ACKNOWLEDGEMENTS

The presenter is the trainee of Food and Drug Regulatory Affairs and Advanced Professional MPH programs of Yale School of Public Health. He is currently an assistant professor of Microbial Food Safety/Epidemiology in Nashville, TN. Relevant extramural funding support from the United States Department of Agriculture, National Institute of Food and Agriculture is appreciated by the corresponding author (USDA NIFA Award numbers: 2016-70020-25805). Content of the presentation does not necessarily reflect the views of the funding agency. Further information and copy of the presentation is available by contacting: aliyar.fouladkhal@aya.yale.edu | (970) 690-7392.

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