Development of a risk ranking tool for evaluating hazards and risks related to agricultural water Subpart E

Summary

To enhance industry **and** regulatory confidence in making risk-based decisions on agricultural water and its use, our team is building a risk ranking tool, backed by quantitative microbial risk assessment (QMRA), that allows users to identify hazards and practices that increase potential risk as well as mitigation strategies that reduce risk applicable to their production system. This project uses historical laboratory and field data coupled with QMRA to quantify the impact of microbiological risk due to growing practices outlined by FDA in Subpart E. This effort to develop resources for industry will enable improved evaluation of risk posed by agricultural water use during production of covered produce and provide scientific evidence to aid in risk reduction and support regulatory compliance.

Benefits to the Industry

This project will provide the produce industry with scientific data related to the cumulative benefits and tradeoffs of various agricultural water use practices on human health risk. Because so few QMRAs have been conducted on agricultural water taking into consideration production-specific information rather than relying on literature assumptions, we believe this information is critical to inform grower and regulator decision making related to the use of agricultural water and informing decisions based on Subpart E. We will use collected data and assessments to inform industry of the impact of various water use scenarios on risk as outlined in Subpart E and potential ways to reduce risks based on real-world growing practices and mitigation measures.

Objectives

1. Identify and gather historical laboratory and field-based data on the presence and persistence of microbial pathogens and indicators in produce production systems with a specific focus on agricultural production water under the context of Subpart E.
2. Using gathered data, develop a QMRA tool that will encompass probabilistic assessment of factors influencing pathogen survival and risk to produce.
3. Integrate pathogen and indicator datasets into the QMRA tool to quantify relative risk implications of spatial, temporal, and crop-specific variables.
4. Develop tailored case studies for agricultural water use that represent diverse growing conditions across the country.

Methods

This project convened experts from produce-growing regions to assess hazards and relative risk in relation to FSMA Subpart E. Leveraging subject matter experts, historical datasets, and new field data, the team refined a quantitative microbial risk assessment (QMRA) to address regulatory requirements. An interactive, web-based QMRA tool is currently being developed using RStudio's Shiny platform, integrating probabilistic modeling of factors influencing pathogen survival and die-off. This tool will quantify microbial risks, enabling comparative evaluation of intervention strategies to achieve specified risk targets. While broadly applicable for agricultural risk characterization, the tool is specifically designed to aid industry stakeholders and regulatory agencies in developing risk-based assessments to inform agricultural water use decisions under Subpart E. The framework supports science-based policy and risk management in produce safety systems.

Results to Date

Using historical datasets and identified gaps, the Delphi method was used to query industry and subject matter experts on risks related to Subpart E. Nine academia (N=9) and thirteen industry (N=13) responses were recorded, with 77% of respondents from grower/food safety roles. Only 41% of responses aligned on top agricultural water risks, highlighting the need for calibration on interpretation of hazards and associated risks (**Figure 1**). Published data show limited information on environmental conditions and crop factors affecting pathogen survival. Field trials indicate initial contamination levels and water application method strongly influencing bacterial survival, with larger sample volumes (≥375 g) improving detection (**Figures 2–4**) Currently, the Arizona State University team is developing the iRISK tool in R Shiny, which will integrate datasets from objectives 1 and 2 and be refined with stakeholder input.

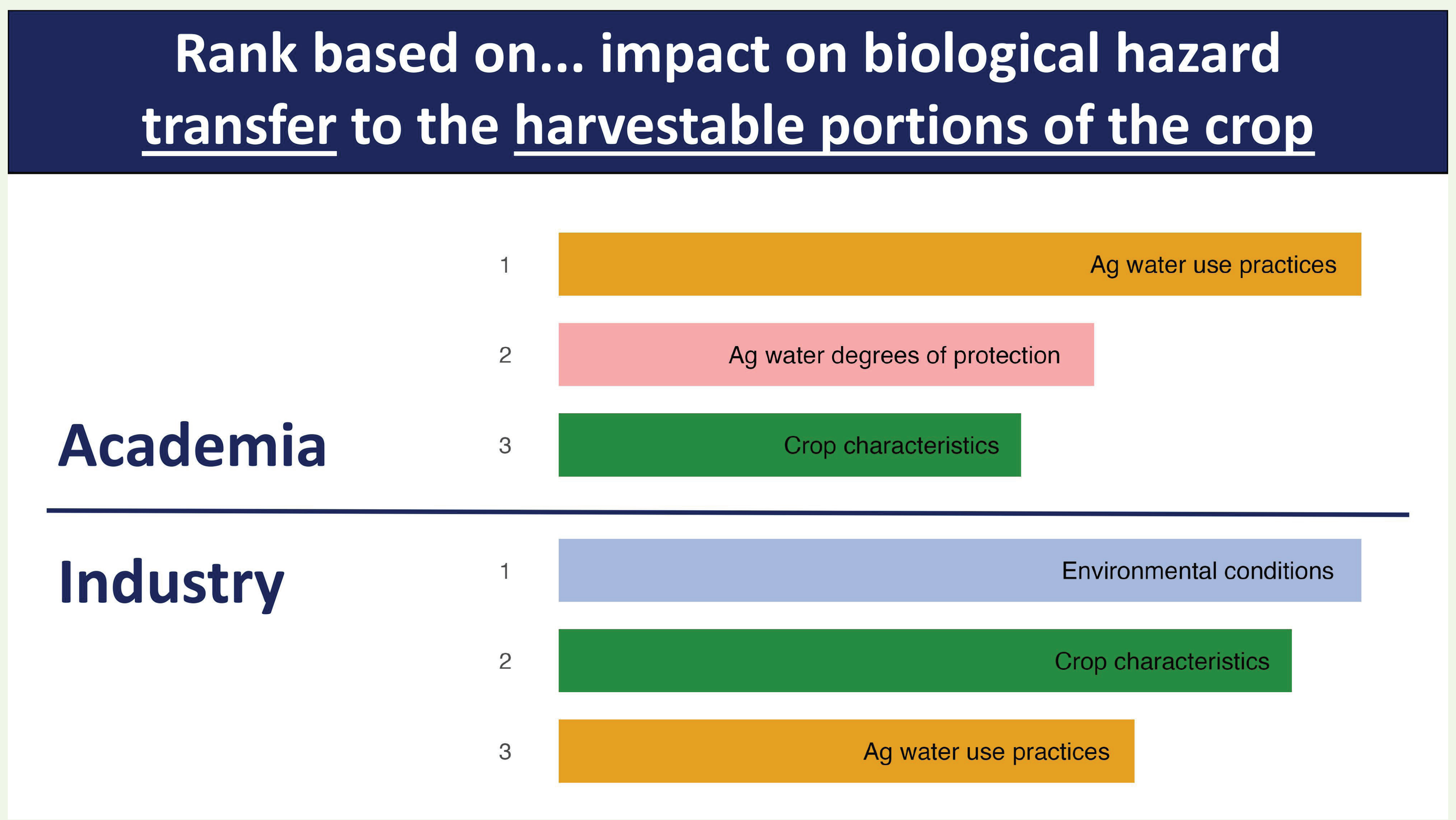

Figure 1: Comparison of academia vs. industry responses on hazard transfer to crop

Figure 2: Whole-head romaine lettuce sample collection

Figure 3: 250-g lettuce composite enrichment

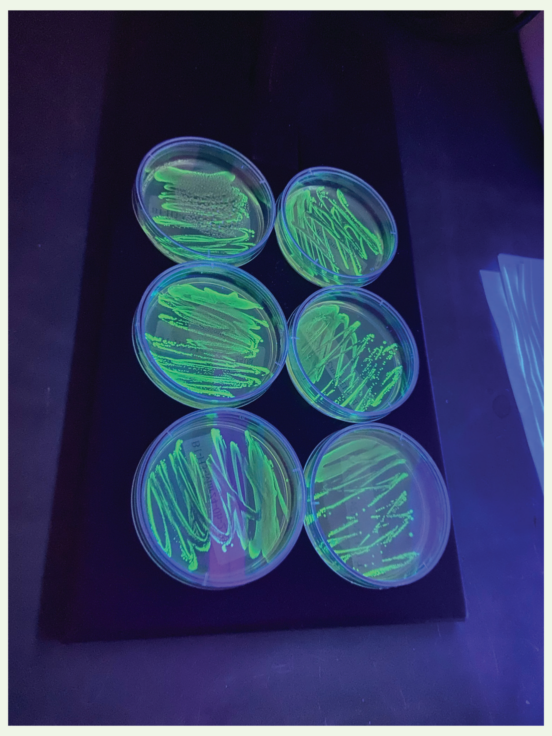

Figure 4: Positive confirmation of green fluorescent protein–tagged *E. coli* bacterial growth

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