“Developing Consensus Produce Safety Metrics for Leafy Greens and Tomatoes” 2011-2016

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Acknowledgements

- SCRI Team
- Produce Industry
  - United Fresh
- FDA
  - Risk assessment division and FSMA produce safety team
- USDA ARS
  - BARC
- NIFA

Status of Key Produce Safety Regulations

- **Two new regulations under the FDA Food Safety Modernization Act of 2011 will dramatically impact the production and marketing of specialty crops**
  - **"Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Proposed Rule,"**
    - **Final rule published November 27, 2015**
  - **"Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Proposed Rule"**
    - **Final rule published September 17, 2015**

Food Safety Metrics

- **One cannot regulate what they cannot readily measure and document**

- **Establishing the stringency of a food control system is meaningless unless compliance can be objectively verified**

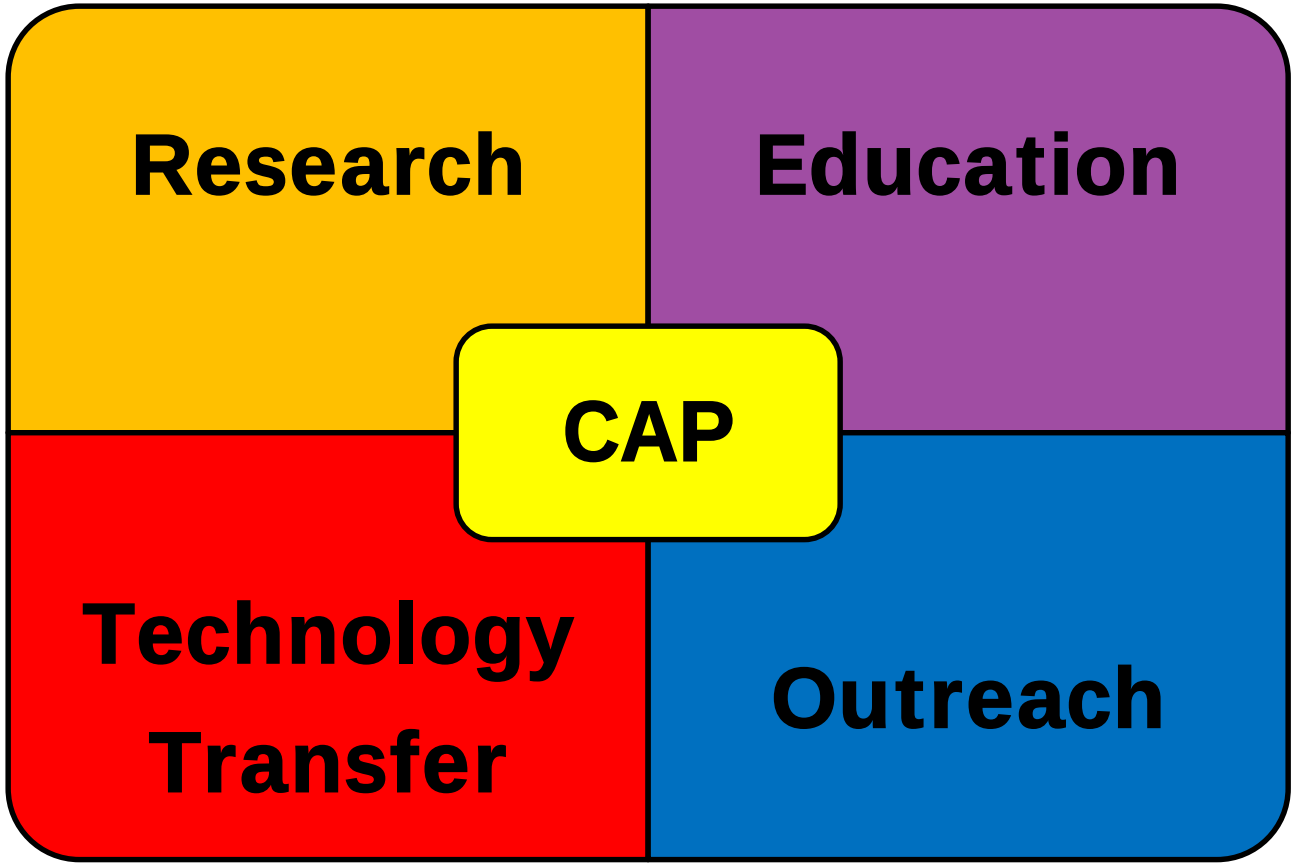
Challenge for Produce Safety Regulation

- Many of the standards and guidelines in the proposed regulation were based on minimal scientific data
  - Data acquired in laboratories and not in field
  - Much of data is specific to certain regions of the country and not available for others
  - Data were not equally available for different sectors
    - e.g., Large farms, small farmers, organic farms

SCRI/CAP Grant

- Consortium of eight universities, two federal agencies, and the produce industry proposed to address this national need via a two-phase SCRI-CAP
  - Phase 1. A 3-year, $5.4M grant from NIFA for targeted field studies and supporting "green house" studies to obtain the science
  - Phase 2. A $4.6M 2-year extension with a focus on validation of the findings of phase 1
- A requirement of the SCRI-CAP grant was 100% matching "in-kind" support from the industry
- Total investment: $20M investment

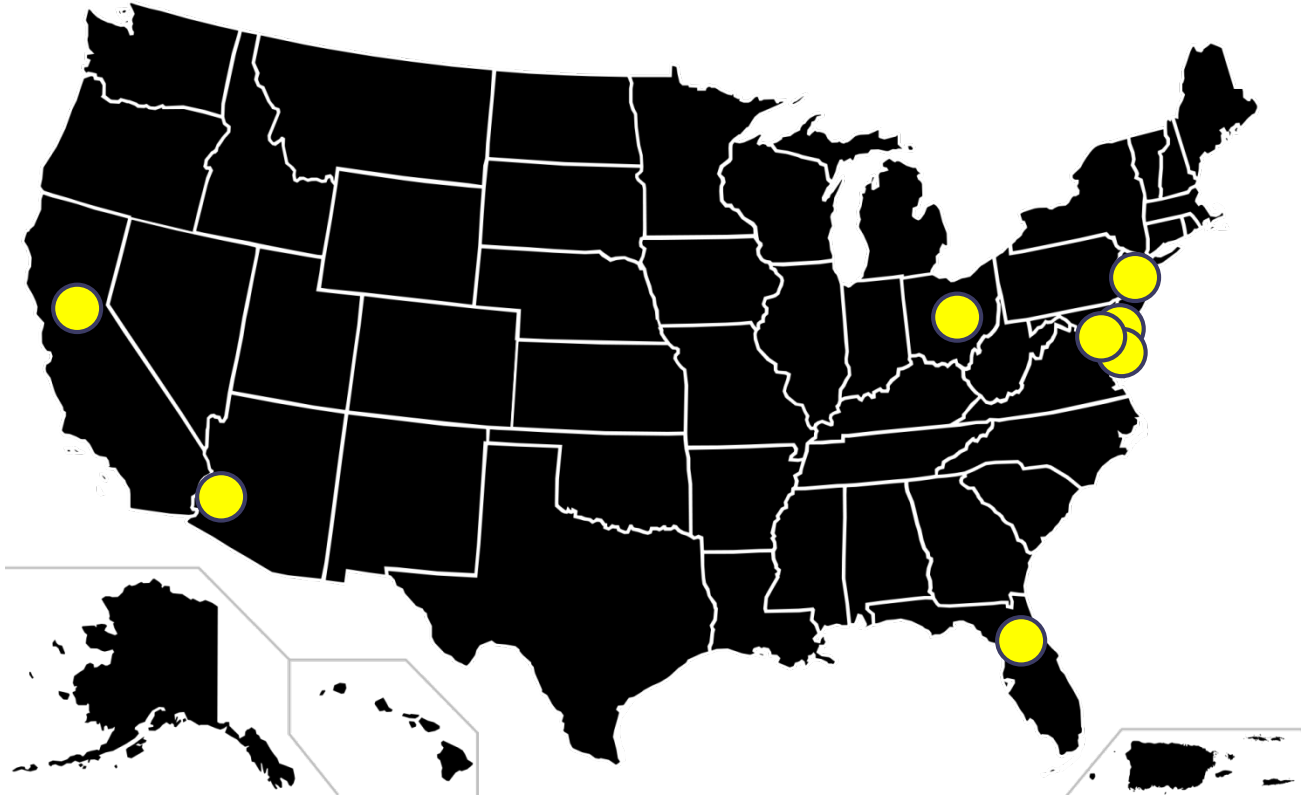
NIFA SCRI CAP Grants



Research Team

- University of Maryland
- Rutgers University
- University of Florida
- University of Delaware
- Ohio State University
- University of California Davis
- University of Maryland Eastern Shore
- University of Arizona Yuma
- USDA/ARS/BARC
- HHS/FDA/CFSAN
- Industry Liaisons
- Produce Industry

Research Team's Locations



The Purpose

- **The long term goals of the CAP grant are:**
  - **Help the produce industry develop and validate scientifically supportable food safety metrics that are applicable in a variety of growing regions and countries**
  - **Provide scientific and technological knowledge to develop other metrics important to enhancing produce food safety**
  - **Identify improved approaches and techniques that allow for the attainment of metrics to be verified simply and cost effectively**

General Approach

- **The focus has been on field studies with additional scientific support as needed provided by "green house" studies or if necessary laboratory models**

- **The five year project was roughly divided into two phase**
  - **Years 1-3: Focus acquiring missing scientific information**
  - **Years 4-5: Acquisition of validation data under commercial conditions**

Project Phases

Phase 1: Scientific Research & Field Trials

- Objective A: Industry Data
- Objective B: Water Sources & Use
- Objective C: Environmental Parameters
- Objective D: Harvesting and Processing
- Objective E: Appropriate Temperature Control & Food Safety Chain Management
- Objective F: Informatics, Data Analysis & Risk Assessment
- Objective G: Consensus Produce Safety Metrics
- Objective H: Extension, Outreach & Education

Phase 2: Validation Trials

- 1. 5ft. No-Harvest Zone
- 2. Time delay in harvest between rainfall events
- 3. Frequency/duration of water testing after a rainfall event
- 4. Dump tank and flume water temperature standards
- 5. Setback distances to prevent airborne transmission of dry manure
- 6. Setting a harvest zone for flooded fields
- 7. Determining effective sampling schemes for microbiological testing

Extension, Education & Outreach Activities

- Produce Safety Website (UFL)
- Training & Tutorials for Mid-Atlantic, Florida, and California Growers
- Multi-disciplinary produce safety course offered at UM, UD, UFL
- Incorporation of new information into JIFSAN international GAP training

Key Findings from Phase 1

- **Increased levels of contamination after a rainfall, but returns to baseline in 3 – 7 days**
  - **Delay harvest if significant rainfall just prior to harvest**
- **The impact of weather events on the microbial quality of various agricultural water sources varies between states and amongst sites within states.**
  - **Important for growers to establish a baseline for their water sources and concentrate monitoring and testing activities close to harvest and following weather events**
- **Poultry litter can travel at least 200 ft. with vegetative barriers in place and at least 400 ft. without vegetative barriers in place.**
  - **While vegetative barriers may mitigate bioaerosol transmission of poultry litter, the current guideline on setback distances (400 ft. in LGMA) is not sufficient to prevent bioaerosol dissemination to adjacent leafy green fields**

Key Findings from Phase 1

- Increased level of bacterial contamination after application of contaminated irrigation water returns to baseline levels within 3 – 7 days
- Time for soil contaminated with fecal material to return to baseline levels varies with region and season
  - Decline takes longer in fall growing seasons
- Flooding events can cause transfer of pathogens through soil depending on :
  - Soil type
  - Moisture content of the soil
  - Slope of the fields
- Data collected generally support the 5-ft no-harvest zone around sites of animal intrusion which has been proposed and is already widely practiced in the industry

Key Findings from Phase 1

- **Research conducted supports the current metric that tomatoes that touch the ground (including bedding material such as plastic) should not be harvested.**
  - **Additionally, all efforts should be made to harvest dry tomatoes**
- **Current sanitizer concentrations to prevent cross contamination in flume systems are higher than necessary**
  - **Specific recommendations to the tomato industry are being developed**
- **Research has indicated that under current contact times the temperature differential is not a significant factor in *Salmonella* internalization into tomatoes**
  - **Specific recommendations to the tomato industry are being developed**

Key Findings from Phase 1

- **Data collected on microbial populations and indicator organisms for re-evaluation of Florida T-Gap requirement for all tomatoes to pass through a packinghouse**
- **Predictive models are being used for improved microbial risk assessments for the survival, growth, and death of pathogens in leafy greens**
- **A computer model was developed to determine the food safety, quality and cost of refrigeration for leafy greens and other produce**
  - **Industry showed interest in this model and being able to use it as a smartphone application**

Phase 2: Key Findings

- Computer program developed for assessing the effectiveness of pre-harvest sampling plans
- Economic data on the likely cost of implementation of the produce regulation to different sectors of the industry key resource for the FDA
- Small farm survey conducted in the Mid-Atlantic states and a second is being conducted in Arizona and California
  - In incidences of foodborne pathogens are consistently low in small-, medium-, and large-scale farms

Impact: FSMA

- **Many of the team's findings were reflected in the final rule, particularly the need for flexibility in relation to regions and seasons:**
  - **Data collected from small farms and cost analysis data are some of the only data available to regulatory agencies.**
  - **Work conducted on microbial quality of water sources support the proposed water testing provision that reduce the frequency of testing depending on the water source.**
    - **Also supports establishing baseline water quality for surface waters**
  - **Manure experiments produce data to assist with the establishment of a rule regarding the application of soil amendments and harvesting of the crop.**

- **How will FSMA affect growers?**
  - **Many small and sustainable growers would most likely be exempt to FSMA regulations, however, those who aren't (mid-sized growers) face significant cost burden than large-sized farms**
  - **Currently seeking more cost data from large-size farms**

Industry Views

- **Through our "Produce Industry Advisory Panel" (PIAP) and the inclusion of representatives from produce industry trade groups on the research team, we have had continuous feedback and industry involvement**
  - **We met formally twice each year with the PIAP and had a similar relationship with FDA**
  - **A significant portion of the research team were extension specialists who work with the small produce industry sector on a daily basis**
- **The various industry sectors have been extremely supportive of the work and have been important resources to the project's overall success**

Future Uses & Next Steps

- **With the publication of the produce safety rule, we will review to determine where we can provide needed information during the remaining time available on our grant**

- **With implementation of the produce safety rule over the next 3 years, we anticipate that there will be a need for additional focused data and knowledge to address scientific issues that arise**

Future Needs

- The publication of the produce safety rule is only the start
- During implementation of the produce safety rule over the next 3 years, you can anticipate a need for even more focused data and knowledge to address scientific issues that will undoubtedly arise
- It is likely that it will take at least a decade to handle all of the challenges to the new regulations

Potential Implementation Challenges

- **Biological Soil Amendments:**
- **Development of practical guidance for control of airborne dissemination of fecal contamination.**
- **Development of methods to objectively determine when human waste has been used, a requirement with no apparent means of enforcement.**
- **Practical means for assessing hold times between application of raw manure and planting of crops, including its use as a side dressing for tree fruit trees.**

- **Pre-harvest Water Quality:**
- **Quantitation of the "die-off" times and conditions needed between exposure to contaminated irrigation water and/or major rain events and harvest that will ensure minimization of microbial contamination.**
- **Identification of alternative "indicator microorganisms" that could effectively replace *Escherichia coli* for the microbiological testing of water, produce, and environments for fecal contamination and effective sanitation. This includes consideration of non-bacterial indicators such as viruses and protozoa**

- **Pre-harvest Practices:**
- **Determination of the conditions and practices for minimizing potential contamination of produce on "mixed-crop" farms (i.e., farms where both animal rearing and produce cultivation take place).**
- **Determination of the potential sources of contamination for stone fruit, avocados, and cucurbits.**
- **Evaluation of means for validating seed treatments or sprouting protocols that can consistently ensure control of pathogenic bacteria growth without the use of active chlorine compounds.**
- **Development of non-lethal means for discouraging intrusion by domestic and feral animals.**

Potential Implementation Challenges

- **Post-harvest Practices:**
- **Determination of protocols and practices needed to ensure effective sanitation of non-metallic surfaces and equipment used in harvesting and packing operations.**
- **Determination of conditions and technologies needed to minimize the extent of infiltration into various fruits and vegetables (e.g., melons, tomatoes, cucumbers) under practical conditions for use in the field, in packing houses, and in fresh-cut operations. This includes finding practical alternatives to hydro-cooling to remove "field heat."**
- **Determination of the optimal temperature for transport and holding of fresh fruits and vegetables that maximize retention of quality while minimizing the growth of pathogenic bacteria.**

- **Decision Tools, Risk Assessments, and Cost/Benefit Analyses:**
- **Development of qualitative and/or quantitative risk assessments and cost/benefit analysis that provide objective means for evaluating potential alternative mitigation strategies.**
- **Development of "decision tools" that allow the complex science underlying the various factors discussed above to be implemented using user friendly application software, including applications suitable for "smart phone platforms."**

- **Education and Extension Activities:**
- **Coordinate with the various produce safety alliances, FDA, state extension agencies, regional produce safety centers of excellence, and trade organizations to disseminate the findings of the studies to the people who need the information in plain and multi-lingual forms.**
- **Develop educational opportunities that will build on the scientific knowledge gained, thereby ensuring continuing improvement in produce safety.**

Observations:
What Worked Well?
What Worked Not So Well?

Composition of the Project

- Highly Diverse
  - Traditional Research Academician
    - Assistant, Associate, and Full Professors
  - Department-based Extension Specialists
  - Field-based Extension Specialists
  - Administrative personnel
  - Industry liaisons
  - Regulatory agency liaisons
  - Federal researchers
- Multiple disciplines

Composition of the Project

- **Managing a team of highly intelligent academic researchers who have diverse areas of interest can be a challenge**
- **Having “sub-objective leads” and “institutional leads” was helpful**

Challenges that Worked Well?

- Putting together the team of researchers took time to gain a joint vision of the project
  - Having extension researchers was critical to reaching small farms, packers and processors
  - Focusing on a team that was “field oriented” a challenge – most academician do not like to leave their labs
  - Convincing researchers that we needed to do the same studies in multiple locations
- Bottom line: We were a team and not an array of researchers each doing their own thing

Challenges that Worked Well?

- **Being able to pay for part of a project coordinator and business manager helped the project, helped NIFA, and allowed the PI to maintain his sanity and do some science and management**

- **Being able to change course as necessary helped ensure that**
  - **We could terminate unproductive lines of research**
  - **We could terminate unproductive members of the research team**

Challenges that Worked Well?

- **The interaction between the research and extension staff worked very well!**
  - **The extension specialist housed in departments served as a good bridge between traditional researchers and field extension personnel**

- **ARS scientists an important resource for the project**
  - **Worked well with university personnel**
  - **Are less familiar with the administrative requirements associated with NIFA grant management**

Challenges That Had to Be Overcome

- Most researchers have little understanding of how regulations are developed
- Issue related to confidentiality took a great deal of time
  - Regulatory considerations vs. need for research data
  - Trust can take a great deal of time
  - Detection of pathogens vs. public health concerns
- Being able to rapidly respond during validation phase is a major challenge

Challenges That Had to Be Overcome

- **Need for equipment, equipment maintenance, facilities/field costs continues to be a systemic problem**

- **Weather!!!!!!!**