

# Food Safety & Defense Research at Full Production Scale

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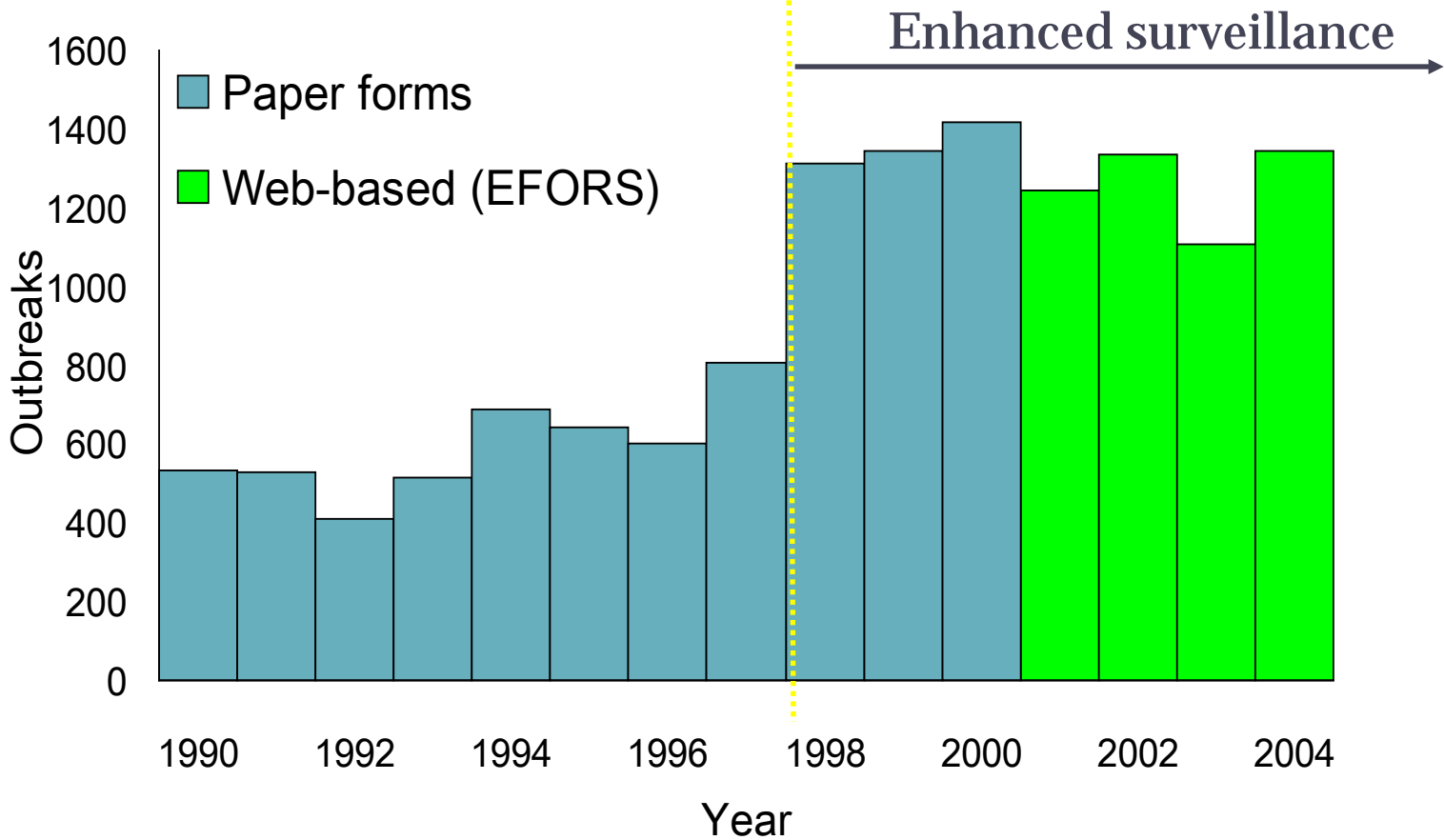
# Presentation

- **Focus will be:**
  - **Microbiological safety of fresh and fresh-cut produce**
    - **Pre-harvest**
    - **Post-harvest**
  - **Impediments to doing research under commercial conditions vs. criticality of industry data**
  - **Regulatory requirements associated with such research**
  - **Alternatives approaches**
  - **Concluding remarks**

# The Challenge of Produce Safety



# Produce Associated Outbreaks Reported to CDC, 1990 - 2004



# Produce Outbreaks by Commodity

## Leafy Greens

Lettuce

Romaine

Mixed lettuce

Cabbage

Spinach

Basil

Parsley

Cilantro

Mesclun

## Melons

Cantaloupe

Honeydew

Watermelon

Other melons

## Tomatoes

Carrots

Green onions

Raspberries

Strawberries

Mango

Almonds

Green grapes

Peppers

Snow Peas

Baby Corn

Squash

Sprouts

Juices

Apple cider

Orange juice

Carrot

# Changing Landscape

- **Changes that could affect produce safety**
  - Increase in amount of produce eaten raw
  - Globalization of the produce industry - extended supply chains
  - Emergence of large scale farming
  - Increased mixing of rural, suburban, and urban environment
  - Close proximity between animal and produce production areas
  - Changes in cultivation, harvesting and distribution practices
  - Emergence of technologies for extending shelf life
  - Increased use of reclaimed water
  - Encouraging wild life habitats

# Challenge of Managing Produce Safety Risks



# Food Policy Concepts

- One cannot regulate what you cannot readily measure and document
- Setting requirements (metrics) is meaningless unless they can be verified
- Must be able to validate that requirements can be met with currently available practices and technologies





# The Challenge

- To be useful as requirements for marketing orders or regulatory programs, such metrics need to be both science-based and risk-based
- If not, there is a strong potential for:
  - Court challenges brought by segments of the domestic industry or other interested parties
  - WTO complaints brought by countries that export to the United States

# The Challenge

- **However to be science-based and risk-based, such metrics must address:**
  - Differences in agricultural approaches among small, medium and large scale cultivation
  - Large regional differences in produce industry in the United States
  - Large differences in produce industries among different countries
  - Large differences in agriculture approaches in developing versus developed countries
  - The increasing demand for “organic” produce

# Diversity!!!



# Proposed FDA Produce Safety Regulation

- **Farm-Specific Food Safety Plans**

- **“Each farm has a unique combination of size, climate, crops grown, current and previous use of its own land and nearby land, sources of agricultural water, growing, harvesting, packing, and holding practices, animal grazing, potential for domestic and wild animals to enter growing or packing areas, and sewage or septic system. Relevant documents on produce safety...recommend that a farm tailor its food safety practices to the practices and conditions at its individual operation.”**

# Proposed FDA Produce Safety Regulation

- **Farm-Specific Food Safety Plans**
  - “While we are not proposing to require farms to conduct an operational assessment or develop a food safety plan, we do recommend that farms do so, because this could help farms be more effective in protecting the safety of their produce.”
- **The likely outcome is that major food marketers will require food safety plans**

# The Challenges

- **Things that work well in the laboratory or during controlled field trials often don't work equally well when implemented commercially**
- **How do you run validation trials that are reflective of pre-harvest commercial operations?**
- **How do you run validation trials that are reflective of post-harvest commercial operations?**
- **How do you assess the impact of distribution, marketing, and home use systems that may amplify produce safety risks**

# Assessing Produce Safety Systems



# The Dilemma

- **There are severe limitations on what can be done to validate and verify commercial operations**
- **If something other than commercial operations and “real pathogens” are used, there will always be residual uncertainty**
- **One cannot test your way to safety**
- **One can use testing to provide a statistically-based level of confidence that control measures are functioning and effective**



# The Wrong Approach

- Don't think about doing an experimental study that involves the direct introduction of a pathogen into a commercial operation that will subsequently release food into commerce!!!!
  - **Regulatory liability**
  - **Civil liability**



Your lawyers after you tell them you just did

# Alternate Approaches

- **Use of attenuated strains:** Likely to require substantial lead time to get approval, particularly if a new strains that is not well documented
- **Surrogate microorganisms:**
  - “Index” vs. “Indicator” microorganisms
  - Example: generic *E. coli* as a predictor of *Salmonella* versus *E. coli* as a predictor of fecal contamination

# Alternate Approaches

- **Use of naturally contaminated material:**
  - **Example: Use of manure that harbors *Salmonella* as a soil amendment**
  - **Gets around prior approval requirements for application but does not remove legal and civil liabilities**
  - **Potential pre-harvest use if do not release materials into commerce (essentially a very large field study)**
  - **Use in post-harvest facilities very questionable from a regulatory standpoint (i.e., purposeful introduction of an adulterated ingredient?)**

# Alternate Approaches

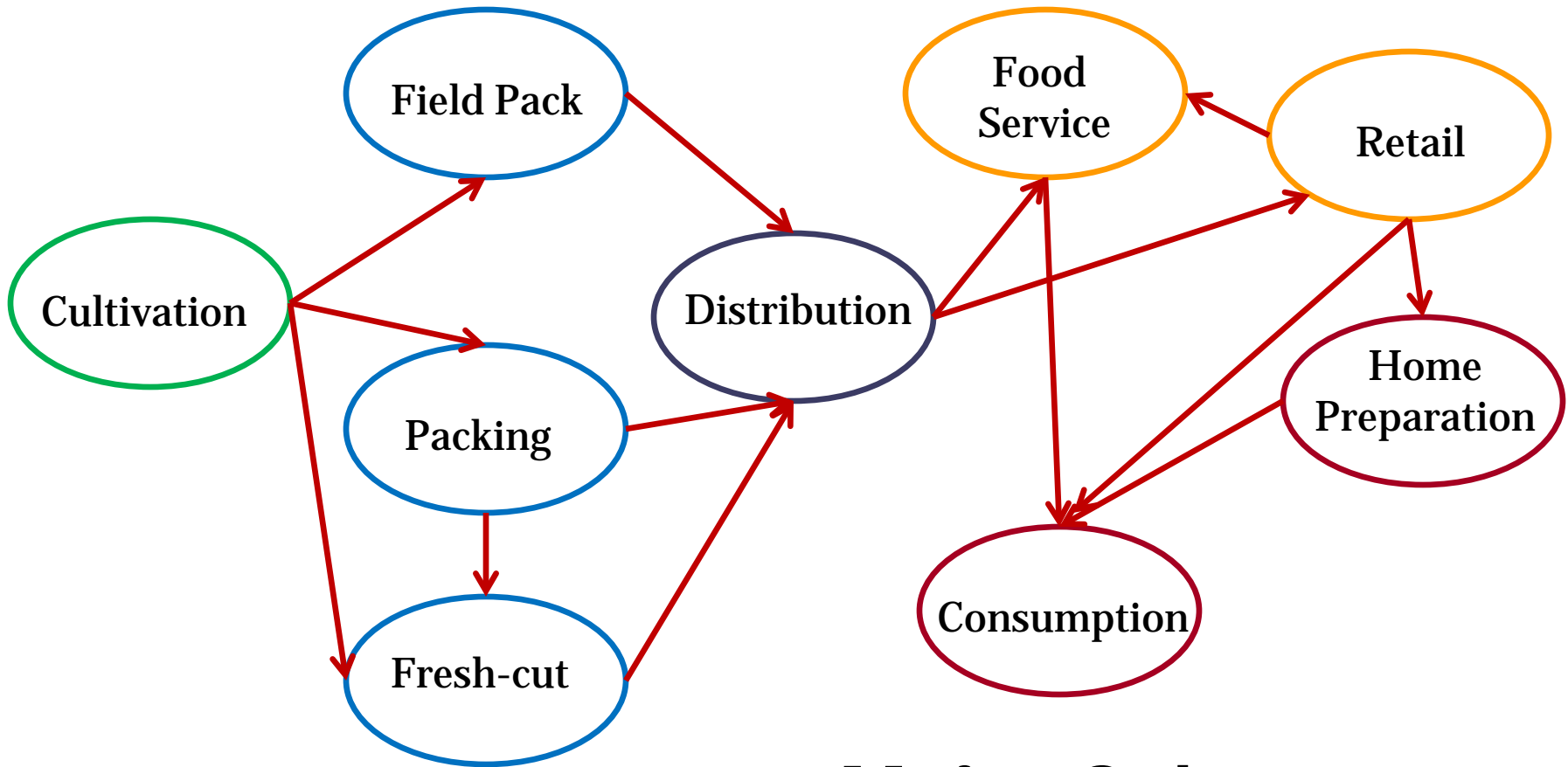
- **Use of naturally contaminated material:**
  - **Two questions to ask yourself before doing such experimentation at the pre-harvest level are:**
    - **What will the neighbors say?**
    - **What will the Washington Post say?**



# Alternate Approaches

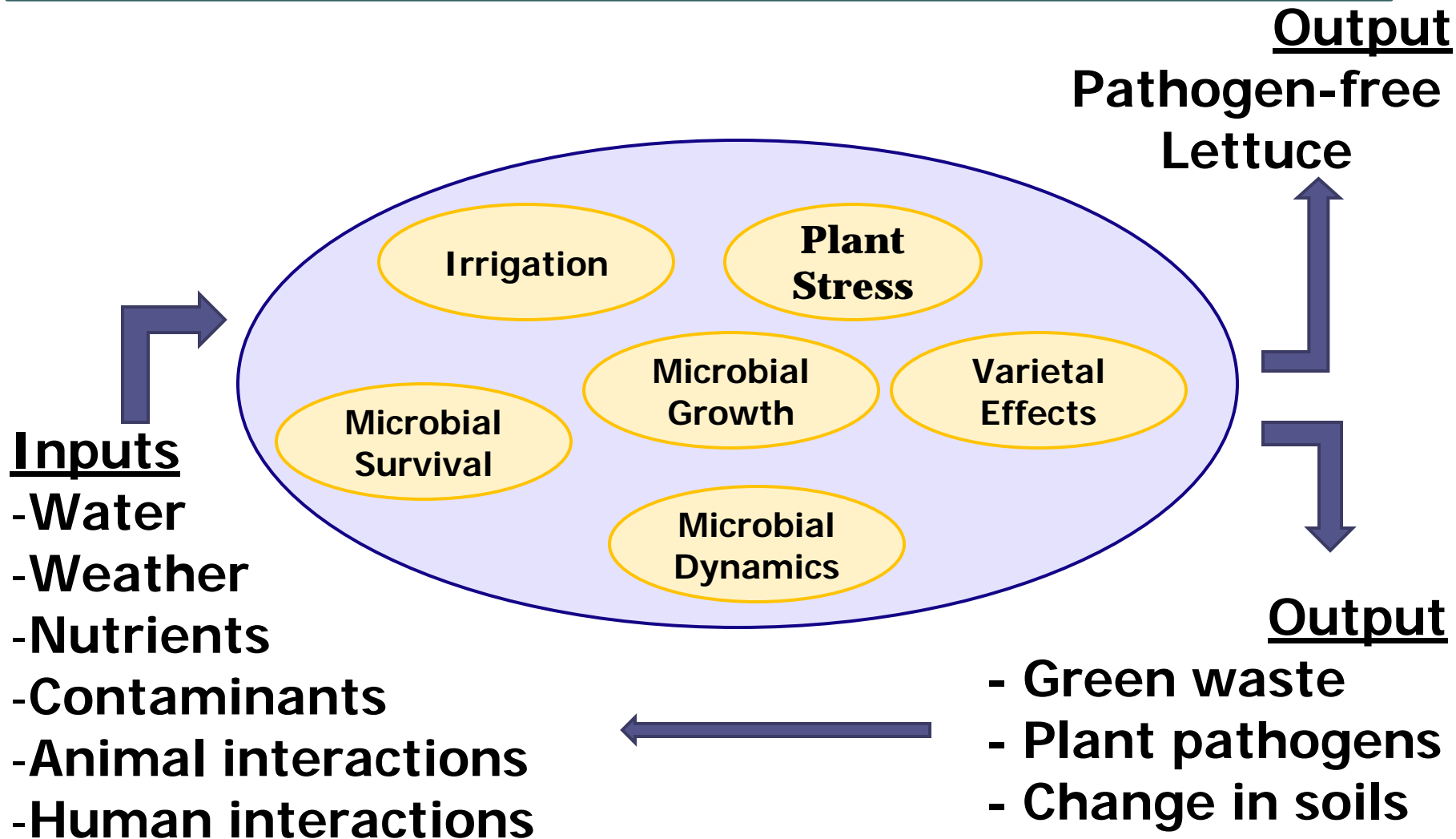
- **Use of Systems/Risk Modeling:**
  - Based on performance and epidemiologic data gained from monitoring of key inputs and outputs from a commercial system
  - Then use modeling techniques to identify key associations and risk factors
  - Support with field and greenhouse studies that underlying causality and quantifiable interactions
  - “Root Cause” analysis very helpful when get non-compliant outputs
  - “Learning system”

# Produce Safety System



**Major Subsystems**

# Hypothetical Sub-system Model: Cultivation



# Personal Observations

- Analytical data are expensive to generate
- Primarily used by industry to provide a yes/no answer
- Ignoring the long term benefits of data collection
- Need to focus on an “informatics” approach to data collection and interpretation





# USDA/NIFA/SCRI Grant

## Developing Scientifically-Based Consensus Food Safety Metrics for Leafy Greens and Tomatoes



<http://cfs3.umd.edu/scri/>

# USDA/NIFA/SCRI CAP Grant

- **The long term goals of the CAP grant are to:**
  - **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 the attainment of the metrics to be verified simply and cost effectively.**

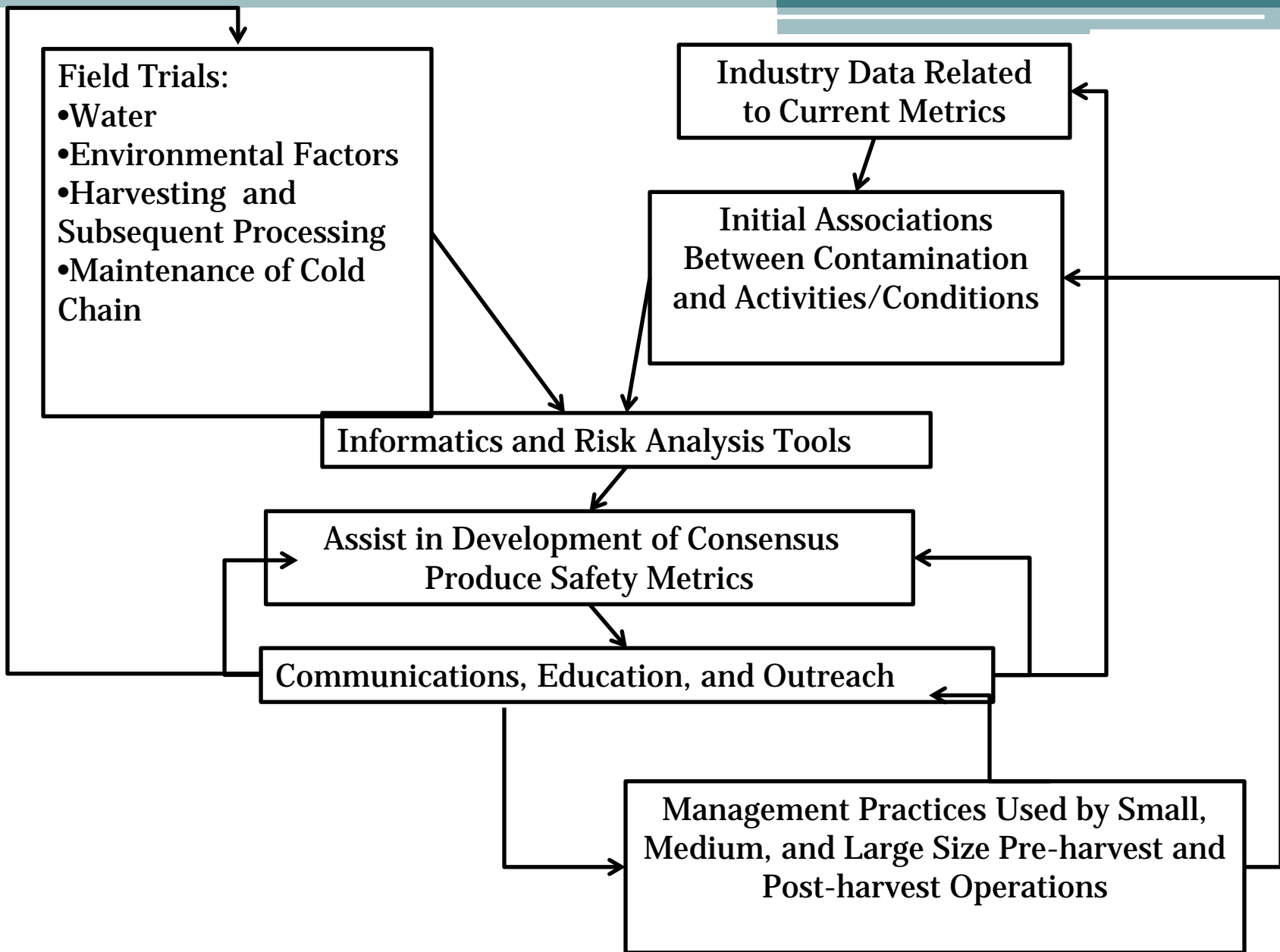
# Research Team

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



# Use of Industry Data

- **Industry microbiological and inspection data is being coupled with data on the key conditions at the cultivation sites to:**
  - **Develop risk factor associations**
  - **Populate risk assessment and economic models**
  - **Combine with field and greenhouse studies to develop predictive models and validate proposed consensus metrics**
- **Types**
  - **Water, produce, compost, distribution temperatures, etc**



# Summary

- **The development of effective produce safety controls requires “facility-specific” pre-harvest and post-harvest food safety plans**
- **Validation trials at the commercial level using real hazards are ill advised**
- **Validation trials with surrogates have uncertainties**
- **Use of systems approaches coupled with modeling has long term benefits**