# Emerging Decision Support Tools for Food Safety in the U.S.

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# The Need for Risk-Based Decision Making

- “If the primary objective of the food safety system is to reduce the burden of disease, success requires risk-based resource allocation. The food safety system must make the best possible use of its resources to reduce the disease burden. This means focusing government effort on the greatest risks and the greatest opportunities to reduce risk, wherever they may arise. It means adopting the interventions—presumably some combination of research, regulation, and education—that will yield the greatest reduction in illness” (Taylor 2002)

# A Vision for Risk-Based Decision Making

- Risk-based decision making is “a systematic means by which to facilitate decision making to reduce public health risk in light of limited resources and additional factors that may be considered” (IOM, 2010)

# Risk Ranking

- “Comparative” risk assessment
- Primary purpose is prioritization
- Models can be categorized based on:
  - Level of complexity
    - Simple → complex
  - Level of quantification
    - Qualitative vs. semi-quantitative
  - Approach to model construction
    - “Top-Down” (epidemiological)
    - “Bottom-Up” (predictive)
  - Degree of scientific rigor

# Model Design Considerations

- Risk Ranking models usually custom designed based on:
  - Specific purpose or designated use
  - Scope
  - Attributes
  - Data sources
  - Resources
- Ideal method should be:
  - Fit-for-purpose
  - Simple, easy to use
  - Data driven
  - Transparent
  - Flexible

# Criteria/Risk Attributes

- Candidate criteria for risk ranking models:
  - Frequency and severity of disease
  - Epidemiological association
  - Likelihood of contamination
  - Size and scope of production or consumption
  - Diversity and complexity of the production chain and industry
  - Potential for agent amplification or control
  - Extent of international trade and economic impact
  - etc.

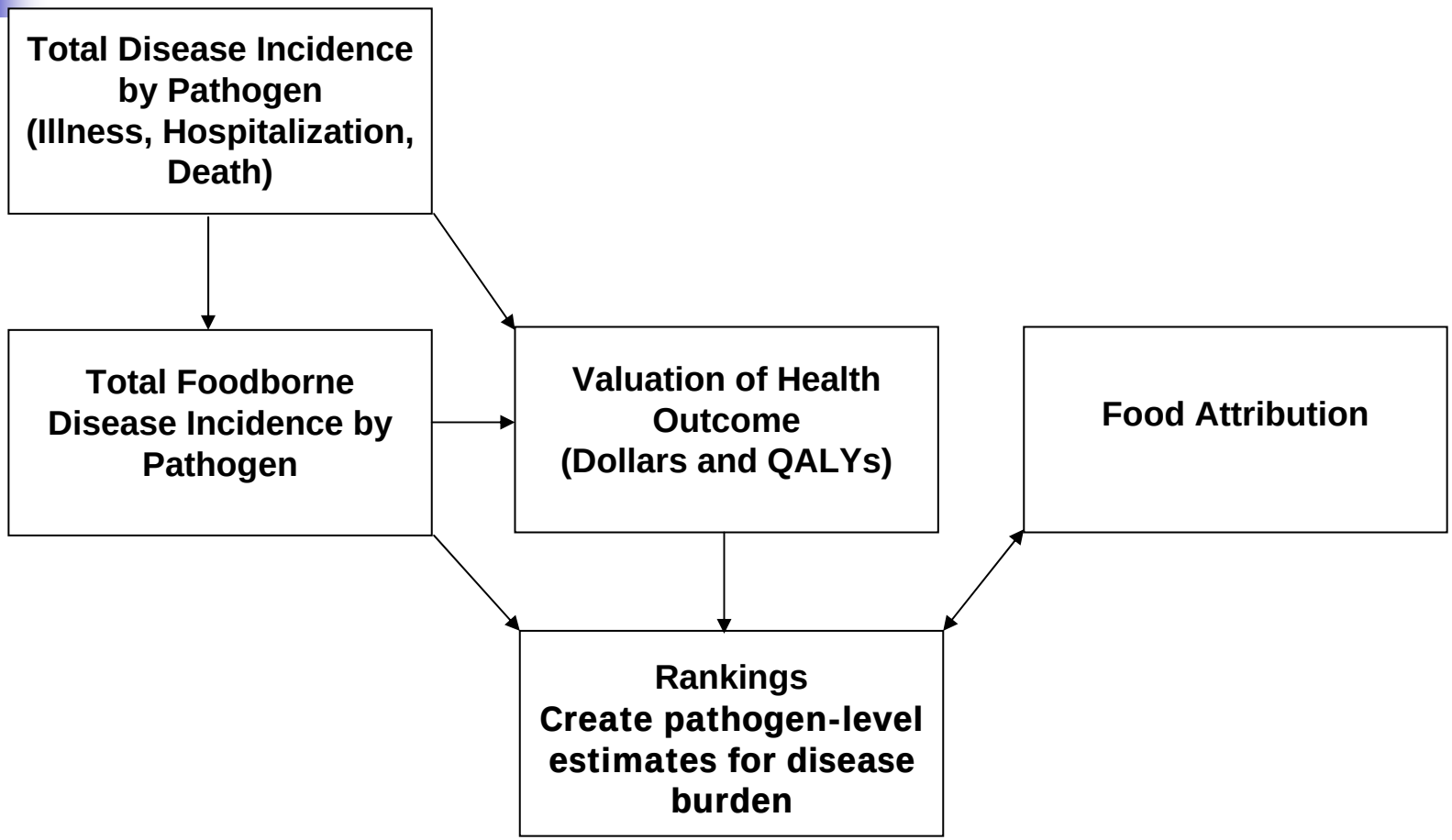
# Semi-Quantitative Models

- Risk Ranger
- Foodborne Illness Risk Ranking Model
- Food Safety Universe Database
- iRisk
- Food Sector Risk Ranking Model

# Foodborne Illness Risk Ranking Model

- Food Safety Research Consortium
- More of a “Top Down” approach
- Three modules
  - Disease incidence
  - Valuation of health outcomes
  - Attribution
- Ranks on five measures of social burden
- Analytica design with user-friendly interface

# FIRRM


Total Disease Incidence by Pathogen (Illness, Hospitalization, Death)
Total Foodborne Disease Incidence by Pathogen
Valuation of Health Outcome (Dollars and QALYs)
Food Attribution
Rankings
Create pathogen-level estimates for disease burden

# iRisk

- IFT, FDA-CFSAN, and Risk Sciences International
- Semi-quantitatively compares risks of hazard-commodity pairs
- Closest to standard MRA paradigm (“bottom-up”):
  - Exposure assessment (populations, consumption)
  - Hazard Characterization (dose-response)
  - Process Information (effect on prevalence and level of contaminant through stages in continuum)
  - Public health metric (pDALY)
- pDALY calculation for ranking purposes
- Analytica platform with web-based user interface

# A New Risk Ranking Effort

- FDA is sponsoring work at RTI International to develop new tools that can be used to analyze the significance of foodborne hazards, prioritize food-related threats to public health, determine future research priorities, and investigate risk mitigation strategies, focusing on
  - pathogen contamination of fresh produce
  - priority pathogen-commodity pairs
  - quantitative, predictive modeling techniques
  - methods to explore risk mitigation strategies

# Key Activities—TO#1

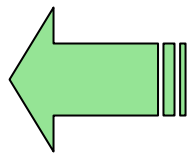
1. Development of a risk ranking approach to prioritize pathogen-commodity pairs for probabilistic modeling using the QPRAM
2. Development of a quantitative predictive risk assessment model (QPRAM) to characterize potential pathogen risks and explore mitigation strategies across the F2F continuum

# Goals for Risk Ranking Tool

- Primary goals that the RR tool and supporting database need to satisfy:
  - Relational DB across multiple “risk” dimensions
  - Readily available sources and PR literature review (roughly 1998 – 2008)
  - Comprehensive, efficient method to prioritize pairs
    - Simple, easy to use
    - Data driven (e.g., little estimation)
    - Transparent
    - Flexible (domestic for now, imported later)
    - Customizable (supports different weighting schemes)

# Outline

- Pathogen-commodity pairs
- Dimensions for risk ranking
  - Data collection
  - Scoring bins
  - Key ranking results
- Risk ranking algorithm
- Risk ranking tool and results
- Conclusions



Four examples

# Identifying Pathogen-Commodity Pairs

- Reviewed epidemiological data on microbiological foodborne disease outbreaks
  - Excluded outbreaks involving multiple commodities
  - Excluded outbreaks involving cooked foods
- Primary data sources included
  - CDC outbreak data on foodborne disease 1996-2006
  - Morbidity & Mortality Weekly Report 1996-2006
  - Peer reviewed literature

# 51 Pathogen-Commodity Pairs

## (12 pathogens, 12 commodity categories)

| Category | # Cases | Pathogen | # Cases | Comments |
|---|---|---|---|---|
| *Berries* (raspberries, strawberries, blackberries) | 1863 | *Cyclospora cayetanensis* | 1391 | Catering (resort, banquet) with raspberries |
| | | Hepatits A Virus | 314 | School with frozen strawberries |
| | | Norovirus | 143 | Predominantly due to strawberries |
| *Citrus* (tomatoes) | 3442 | *Salmonella* spp. | 2162 | Most cases were at a restaurant or deli |
| | | Norovirus | 369 | Half of the cases were from an institution |
| *Leafy greens* (lettuce, spinach, fresh herbs) | 2911 | Enterohemorrhagic *E. coli* | 696 | lettuce (398 cases), spinach (226), parsley (72) Half of the cases were restaurant based |
| | | *Salmonella* spp. | 201 | Predominantly lettuce, some cases from cilantro |
| | | *Shigella* spp. | 507 | Majority of cases associated with parsley |
| | | Norovirus | 316 | All from lettuce, mostly from restaurant, deli or school |
| | | *Cyclospora cayetanensis* | 877 | Most due to basil from restaurant, deli or catering |
| *Melons* (cantaloupe, honeydew, watermelon) | 1656 | *Salmonella* spp. | 432 | Majority of cases from restaurant or institution |
| | | Norovirus | 417 | Majority of cases from restaurant or institution |
| | | Enterohemorrhagic *E. coli* | 736 | One outbreak with watermelon from a restaurant |
| *Root vegetables* (green onions, carrots,potatoes) | 1327 | Hepatits A Virus | 1070 | All cases from green onions at the restaurant |
| | | *Cryptosporidium parvum* | 106 | All cases from green onions at the restaurant |
| *Salad* (lettuce, vegetable, fruit salads) | 6588 | Enterohemorrhagic *E. coli* | 324 | Most cases from lettuce based salads at restaurants |
| | | Norovirus | 5288 | 89/109 from restaurant or catering with lettuce salads |
| | | *Salmonella* spp. | 617 | Most from lettuce based salads in restaurant |

# Choosing RR Dimensions

| ***Concern*** | **Ranking Dimension** |
|---|---|
| *Epidemiological strength* | 1. Epidemiological Linkage (pair)<br>2. Epidemiological Multiplier (path) |
| *Severity of disease* | 3. Hospitalization rates (path)<br>4. Death rates (path) |
| *Pathogen characteristics* | 5. Susceptible populations (path)<br>6. Infectious dose (path) |
| *Commodity characteristics* | 7. Contamination prevalence (pair)<br>8. Consumption (cmdty)<br>9. Growth potential/shelf life (pair) |

# Characterizing RR Dimensions

- Preferred readily available data and information sources (e.g., NHANES, FoodNet)
- Iterative approach used to develop four-bin scoring system from “low” to “high” based on
  - Data set we had to work with
  - Knowledge of pathogen and commodity
  - Feedback from FDA and other experts
- Scoring can be qualitative or quantitative or both, but criteria are explicit (it is or it ain’t)

# Epidemiological Linkage

- Dimension 1 – Strength of evidence linking pathogen, commodity, and foodborne disease
- Key data sources: CDC, MMWR, PR literature

| Score | Category | Outbreaks | Total Cases |
|---|---|---|---|
| 1 | Weak | Any | < 100 |
| 2 | Moderate | 1-2 | 100 – 1000 |
| 3 | Strong | 3-5 | 100 – 1000 |
| 4 | Very strong | 5+ | > 100 |

- Key results:
  - Mixed produce-norovirus
  - Tomatoes-*Salmonella* spp.
  - Leafy greens-*E. coli,* EHEC
  - Sprouts, Salmonella spp.
  - 10 others

# Death Rates

- Dimension 4 – assume commodity-independent
- Key data sources: Mead et al., 1999; FoodNet 1997-2004; PR literature for norovirus and *Giardia lamblia*

| Score | Category | % Death |
|---|---|---|
| 1 | Low | < 0.1% |
| 2 | Medium | 0.1 – 0.5% |
| 3 | Medium High | >0.5 – 1% |
| 4 | High | > 1% |

- Key results:
  - *E. coli,* EHEC*
  - *Salmonella spp.*
  - *Cryptosporidium parvuum*

# Infectious Dose

- Dimension 6 – pathogen-specific characteristic related to severity of effect
- Key data sources: FDA CFSAN and PR literature

| Score | Category | Strength of evidence that ID was: |
|---|---|---|
| 1 | High | 100,000+ |
| 2 | Medium | 1,001 – 100,000 |
| 3 | Low | 101 – 1,000 |
| 4 | Very low | 1 – 100 |

- Key results:
  - 8 pathogens within "Very low," including *Cryptosporidium parvum,* noroviruses, *Giardia lamblia E. coli,* EHEC, *Shigella* spp.

# Consumption

- Dimension 8 – percentage of population consuming produce commodity
- Key data source: NHANES (2004-2005)

| Score | Category | % Consumption in Population |
|---|---|---|
| 1 | Low | < 1% |
| 2 | Medium | 1 – 5% |
| 3 | High | >5 – 10% |
| 4 | Very high | > 10% |

- Key results:
  - Leafy greens
  - Tomatoes

# Risk Ranking Algorithm

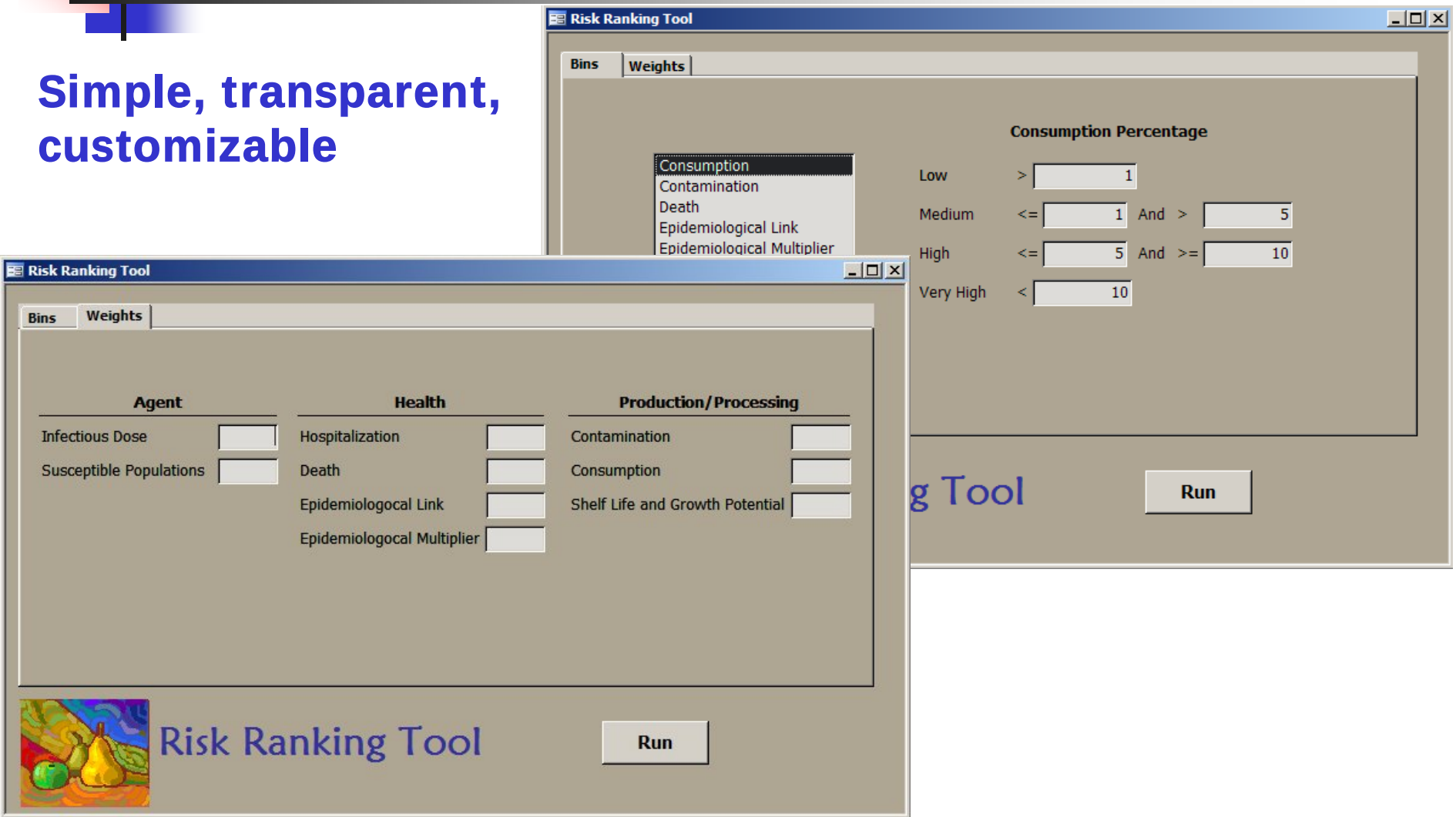
$$\text{Ranking Score} = \sum \text{Score}_i \times \text{Weight}_i$$

- Simple ranking algorithm expected to produce similar results for basic weighting schemes
- Optics and transparency important, so we considered a couple of basic schemes
  - Summing weights to unity
  - Ordinal weights (with or without anchor)
- Ordinal weights chosen for transparency and ease of use (but RR tool is “blind”)

# Risk Ranking Tool

http://www.foodrisk.org/exclusives/RRT/

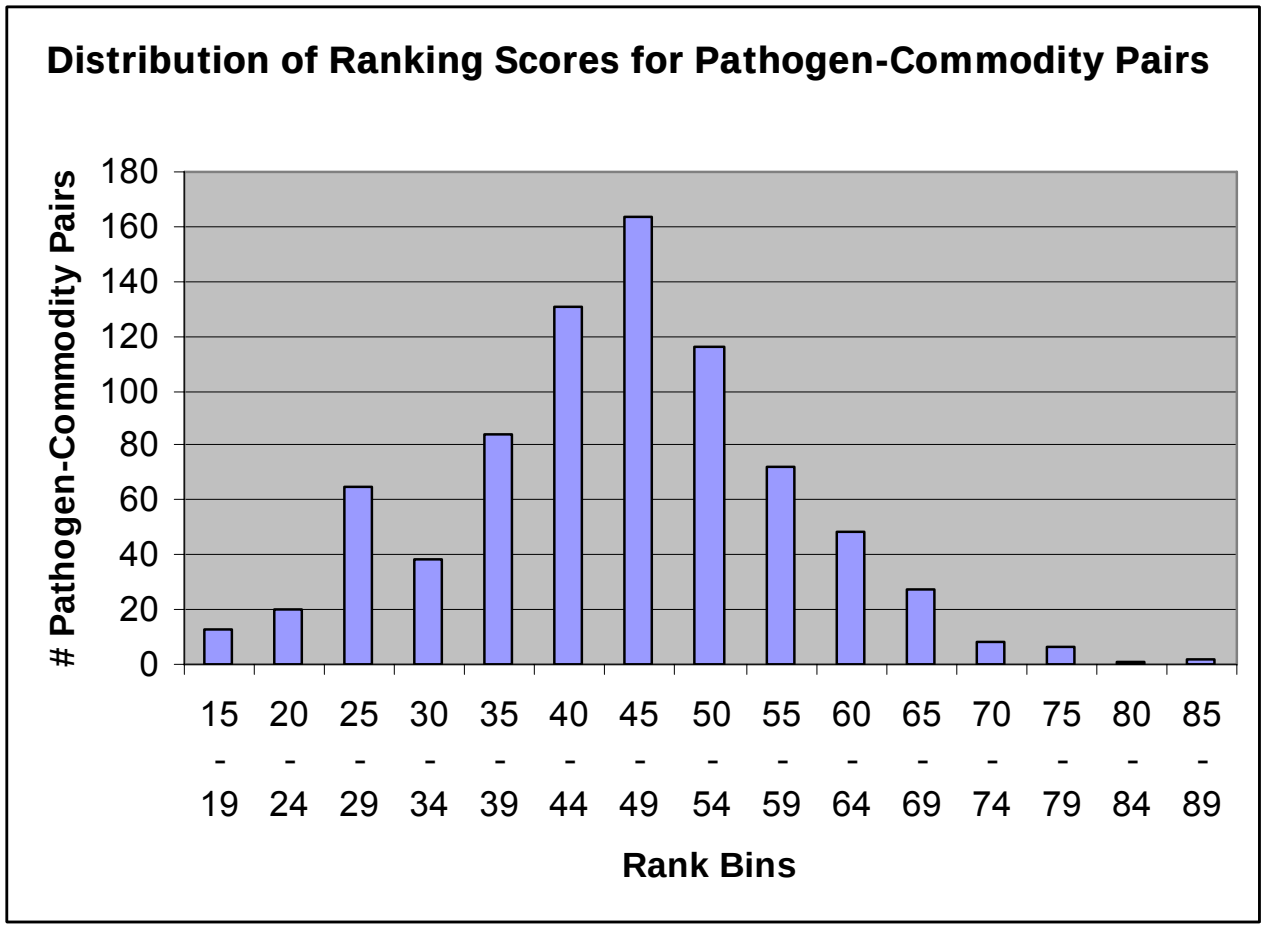
**Simple, transparent, customizable**



# Risk Ranking Tool Results

- Ran a “weighting scenario analysis” to consider the sensitivity of the ranking results to the selected weights
- Ran RR tool for 15 different weighting scenarios with weights for each risk dimension ranging between 1-5
- Plotted the distribution of ranking scores across all 15 scenarios for all pathogen-commodity pairs

# Risk Ranking Tool Results (cont)



# Risk Ranking Tool Results (cont)

| Commodity | Pathogen | Ranking Score | Rank Range |
|---|---|---|---|
| Leafy greens | *E. coli,* EHEC | 72 | 66 – 92 |
| Tomatoes | *Salmonella* spp. | 64 | 58 – 81 |
| Melons | *Salmonella* spp. | 62 | 57 – 78 |
| Leafy greens | *Salmonella* spp. | 60 | 54 – 76 |
| Crucifers | *E. coli,* EHEC | 60 | 54 – 78 |
| Melons | *E. coli,* EHEC | 60 | 54 – 78 |
| Mixed produce | *E. coli,* EHEC | 60 | 54 – 82 |
| Herbs | *E. coli,* EHEC | 54 | 48 – 71 |
| Green onions | *Cryptosporidium parvum* | 53 | 47 – 72 |
| Mangos | *Salmonella* spp. | 52 | 47 – 68 |

# Conclusions

- Pathogen-commodity RR tool = the right tool for the job (i.e., achieved major goals, fit for purpose)
- Results for ordinal weighting scheme consistent with expert opinion on priorities
- Not intended to replace judgment but, rather, to provide customizable interface to test assumptions
- DB extensible to other agents, commodities, and risk dimensions
- Includes both “top down” and “bottom up” data sources
- Data gaps for some dimensions may need to be explored further or addressed through weighting

# Choosing the “Right” Risk Ranking Model

- Degree of resolution
  - Numerical scores vs. “bins”
  - Uncertainty/variability
- Alternative ways to describe inputs/outputs
  - Attribution/PH impacts
  - Measures or indicators
- Weighting for importance
- Interpretation of outputs

# Team Members

- Lee-Ann Jaykus, NCSU
- RTI
  - Maren Anderson
  - Steve Beaulieu
  - Megan Tulloch
- Sherri Dennis, FDA