FEED THE FUTURE
The U.S. Government's Global Hunger & Food Security Initiative

Introduction to Risk-Based Approaches in Food Safety

Feed the Future Innovation Lab for Food Safety

June 7, 2023

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Cornell University

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AGENDA

- **Welcome and Introduction – 5 min.**
  Haley Oliver, FSIL Director, Purdue University
- **Microbial Risk Assessment – 15 min.**
  Arie Havelaar, Professor, University of Florida
- **Risk Assessment at FSIS – 15 min.**
  Joanna Zablotsky-Kufel, Director, RAAS, USDA FSIS
- **Risk Prioritization – 15 min.**
  Juliana Ruzante, Senior Food Safety and Public Health Scientist, RTI International
- **Q&A – 10 min.**

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SPEAKER

Microbial Risk Assessment in Low- and Middle-Income Countries: Challenges and Solutions

Arie Havelaar, PhD

Professor, Global Food Safety & Zoonoses
University of Florida

Microbial risk assessment in low- and middle-income countries
Challenges and solutions

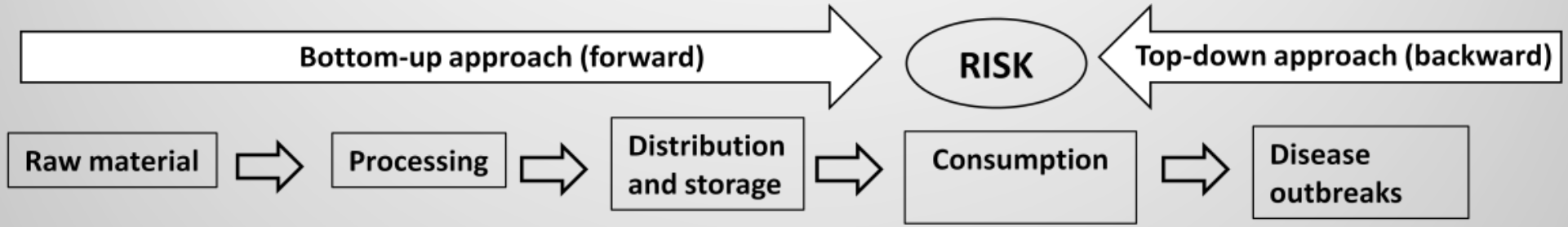
Arie Havelaar, University of Florida

FSIL webinar June 7, 2023

EMERGING PATHOGENS INSTITUTE

UNIVERSITY OF FLORIDA

Two types of microbial risk assessment



- Top-down approach
  - Surveillance, outbreaks and epidemiological studies
  - Attribution to sources
  - Retrospective
- Bottom-up approach
  - Occurrence and dynamics of pathogens in food chains
  - Data and resource intensive
  - Predictive
- Combined approaches may be efficient

EFSA Journal 2012;10(6):2741

Challenges in quantitative microbial risk assessment in LMIC

Bottom-up

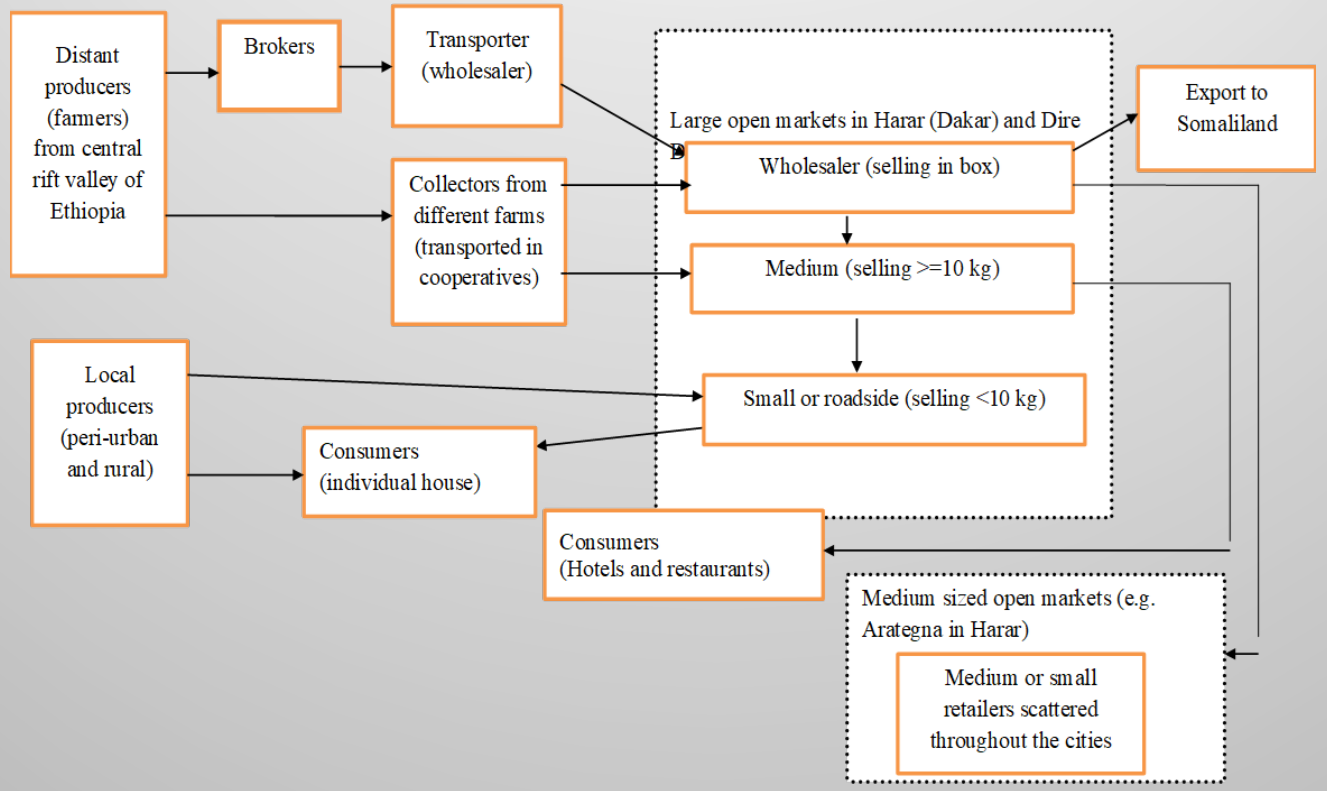
- Statement of purpose
- Hazard identification
- Exposure assessment
  - Informal food chains
  - Fewer data
- Hazard characterization
- Risk characterization
  - Repeated exposures

Top-down

- Incidence of disease, mortality; disease burden
  - WHO FERG data available at subregional level and for 2010
- Attribution of illnesses to food
- Attribution to food groups and specific foods
  - Limited availability of published data

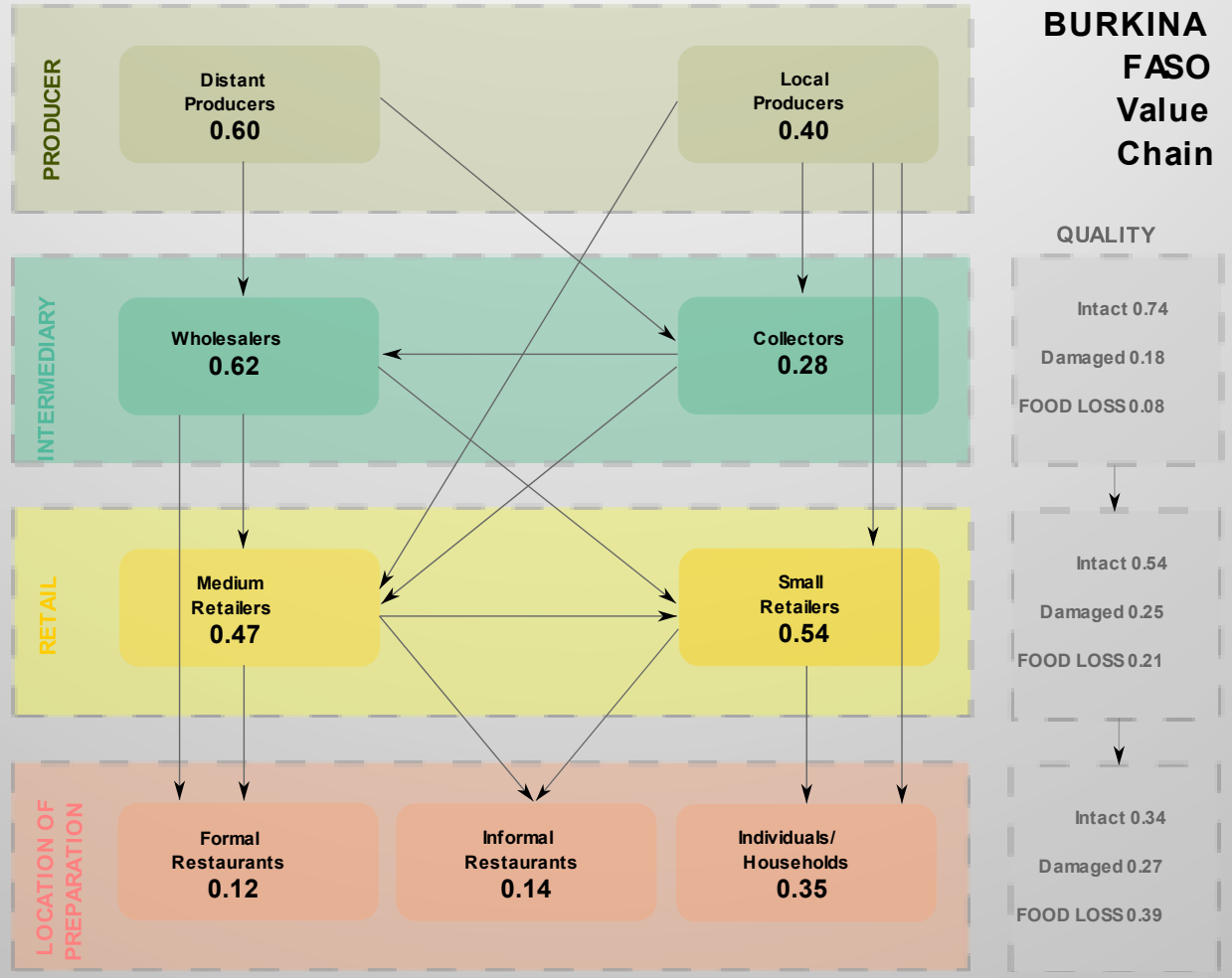
Informal food chains

- Value chain assessment to map food chain structure and product flows



https://cgspace.cgiar.org/handle/10568/114416

Bayesian Belief Networks to quantify informal food chains



Ganser, Barker and Havelaar, unpublished

Challenges in data collection

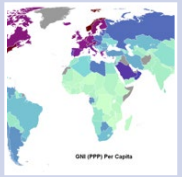
Limited laboratory infrastructure and training in molecular methods

Limited availability of laboratory supplies

Increasingly stringent import and export requirements

Limited sustainability of capacity building efforts beyond projects

Overcoming challenges in data collection



Borrow data from high-income countries

Project-based capacity building and strategic sampling / analysis
Study design
Advanced data analytics

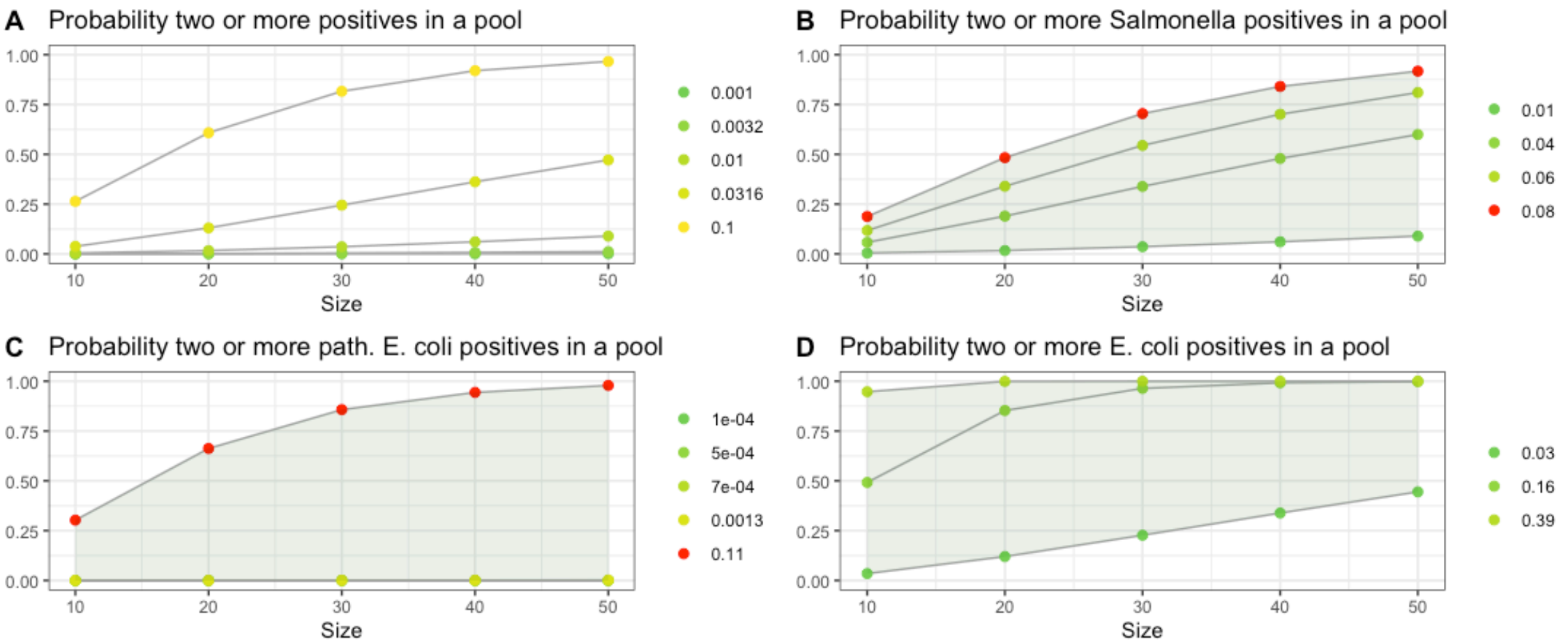
Expert elicitation

Long-term investment in institutional partnerships

Decolonizing science

Open Access publishing

Pooling to test the prevalence of pathogens on tomatoes



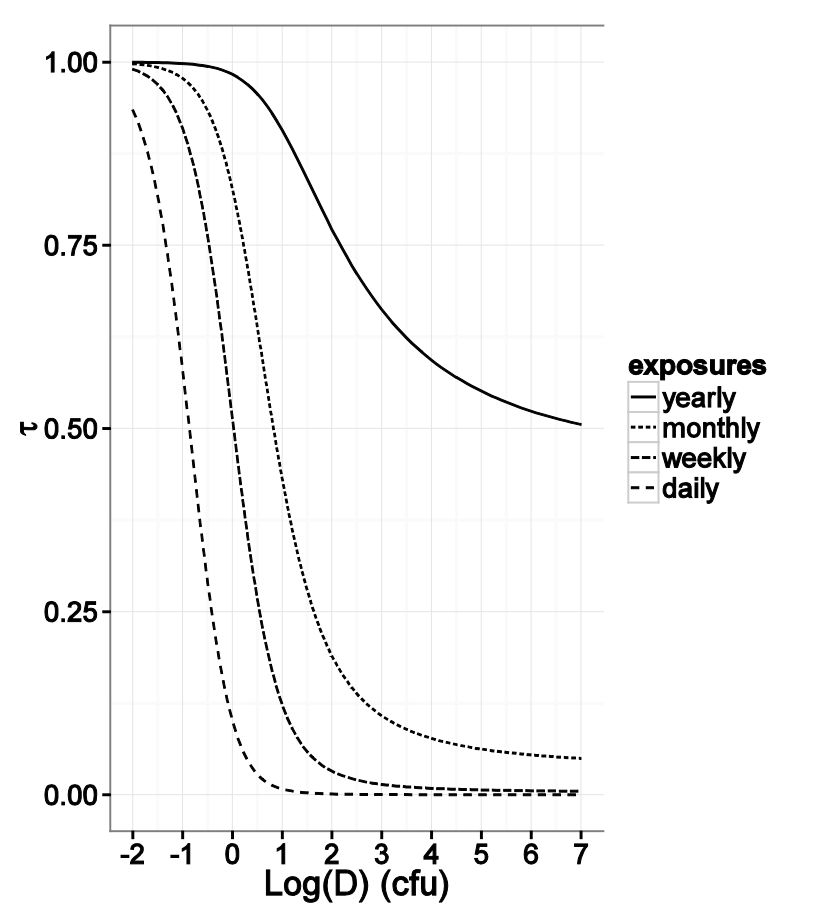
Havelaar and Ganser, unpublished

Repeated exposures

Risk characterization often assumes subsequent exposures are independent

Acquired immunity may violate this assumption, resulting in overestimation of risk

Combine standard QMRA models with dynamic infectious disease models



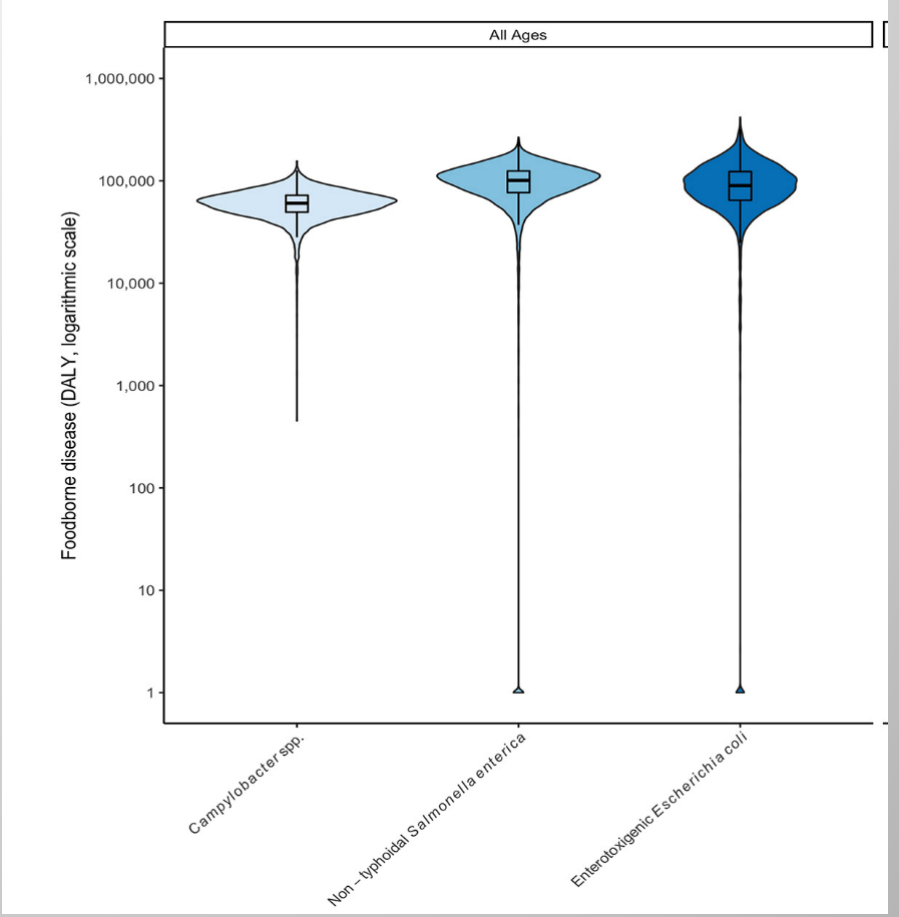
Havelaar and Swart, Risk Anal 2014;34:1807-1819

WHO FERG data to support decision making at country level

Access and publication needs permission from national governments

Approvals obtained from Ethiopia, Burkina Faso, Rwanda

Updated from 2010 to 2017 based on trends in data from Global Burden of Disease study (https://vizhub.healthdata.org/gbd-compare/)



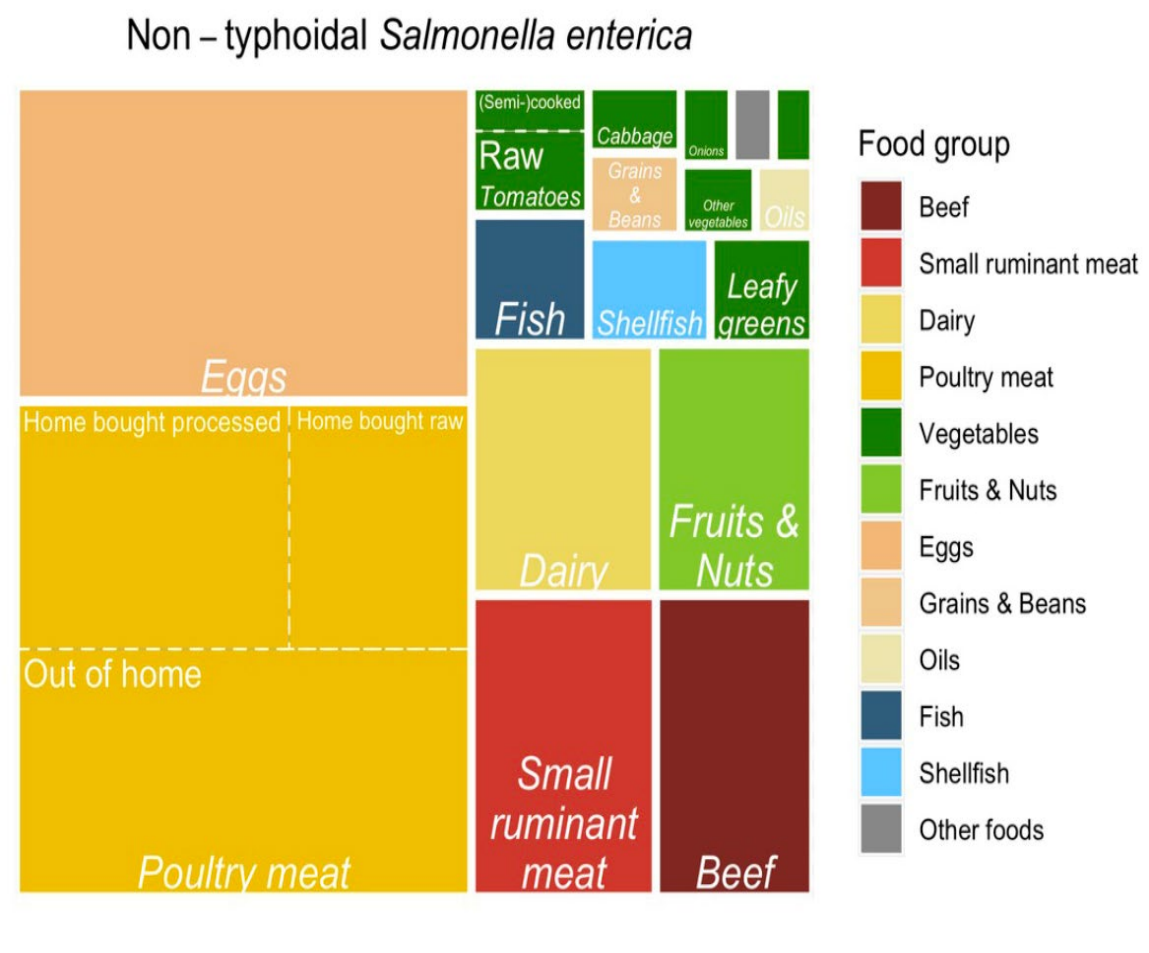
Havelaar et al., Frontiers Sust Food Sys 2022;6:1024560

Attribution to food groups and products

Studies in three countries

WHO FERG data available for attributing selected zoonotic foodborne pathogens to food groups

Country-specific Structured Expert Elicitation to provide additional data



Sapp et al., PLOS NTD 2022;16:e0010663

Disease burden of dairy products in Rwanda

Table 5 Disease burden associated with dairy consumption in Rwanda, 2010 (total population)

A. All dairy groups

Hazard	Incidence (x 1,000)	Incidence per 100,000	Mortality	Mortality per 100,000	DALY (x 1000)	DALY per 100,000
Campylobacter spp.	44.6 (0.9–172)^	411 (8 – 1,590)	12.5 (0.4–31.8)	0.12 (0.00-0.29)	1.15 (0.41–2.91)	10.6 (0.4–26.9)
Non-typhoidal *S. enterica*	7.56 (0.00-315)	69.7 (0.0-291)	11.3 (0.0–37.0)	0.11 (0.00-0.34)	0.85 (0.00-2.78)	7.87 (0.00-25.7)
Cryptosporidium spp.	4.47 (0.00-29.8)	41.2 (0.0-275)	3.06 (0.00–18.0)	0.03 (0.00-0.17)	0.25 (0.00-1.50)	2.35 (0.00-13.9)
Brucella spp.	0.65 (0.00-4.48)	6.02 (0.00-41.3)	3.28 (0.00-23.3)	0.03 (0.00-0.22)	0.21 (0.00-1.46)	1.92 (0.00-13.5)
Mycobacterium bovis	0.27 (0.17–0.35)	2.46 (1.60–3.20)	24.8 (10.9–45.3)	0.23 (0.10–0.42)	1.41 (0.66–2.51)	13.0 (6.1–23.2)
Total burden	57.5 (6.6–190)	531 (61 – 1,750)	54.9 (25.8–99.0)	0.51 (0.24–0.91)	3.87 (1.73–7.16)	35.7 (16.0–66.0)

^ Mean (95% uncertainty interval)

B. Raw cattle milk consumption

Hazard	Incidence (x 1,000)	Incidence per 100,000	Mortality	Mortality per 100,000	DALY (x 1000)	DALY per 100,000
Campylobacter spp.	7.33 (0.00-33.5)^	67.6 (0.0-309)	2.04 (0.00-6.84)	0.02 (0.00-0.06)	0.18 (0.00-0.63)	1.74 (0.00-5.81)
Non-typhoidal *S. enterica*	3.48 (0.00-15.5)	32.1 (0.0-143)	5.21 (0.00–19.0)	0.05 (0.00-0.18)	0.39 (0.00-1.42)	3.62 (0.00-13.2)
Cryptosporidium spp.	1.92 (0.00-13.4)	17.7 (0.0-124)	1.32 (0.00-8.50)	0.01 (0.00-0.08)	0.11 (0.00-0.71)	1.01 (0.00-6.55)
Brucella spp.	0.38 (0.00-2.87)	3.52 (0.00-26.5)	1.92 (0.00-14.4)	0.02 (0.00-0.13)	0.12 (0.00-0.91)	1.13 (0.00-8.41)
Mycobacterium bovis	0.17 (0.05–0.28)	1.56 (0.43–2.59)	15.7 (3.5–33.0)	0.15 (0.03–0.30)	0.89 (0.20–1.84)	8.23 (1.81-17.0)
Total burden	13.3 (1.2–46)	123 (11–425)	26.2 (6.6–56.1)	0.24 (0.06–0.52)	1.70 (0.44–3.73)	15.7 (4.1–34.4)

^ Mean (95% uncertainty interval)

Acknowledgments

- Amanda Sapp, Claudia Ganser, Mirna Amaya, Nitya Singh, Arno Swart
- Funding
  - Bill & Melinda Gates Foundation
  - UK Foreign and Commonwealth Development Office
  - Feed the Future Food Safety Innovation Lab
- Projects
  - Pull Push https://www.ilri.org/research/projects/urban-food-markets-africa-incentivizing-food-safety-using-pull-push-approach
  - TARTARE https://foodsafety.osu.edu/research/international-research-shifting-food-safety-paradigm/tartare
  - Chakula Salama https://foodsafety.osu.edu/research/chakula-salama

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SPEAKER

Science in Action: Development, Conduct, and Utilization of Quantitative Risk Assessments at FSIS

Joanna Zablotsky-Kufel, PhD

Director, Risk Assessment & Analytics Staff

USDA Food Safety & Inspection Service

Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Science in Action: Development, Conduct, and Utilization of Quantitative Risk Assessments at FSIS

Dr. Joanna Zablotsky Kufel
Director, Risk Assessment and Analytics Staff (RAAS)
Office of Public Health Science
Food Safety and Inspection Service
United States Department of Agriculture

June 7th, 2023
Introduction to Risk-Based Approaches in Food Safety
Feed the Future Innovation Lab for Food Safety

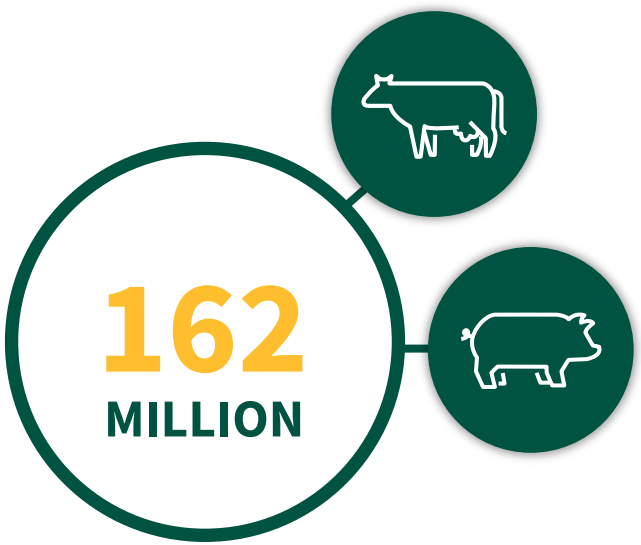
Our Mission

The Food Safety and Inspection Service is responsible for ensuring that meat, poultry and egg products are safe, wholesome and properly labeled.

Our Vision

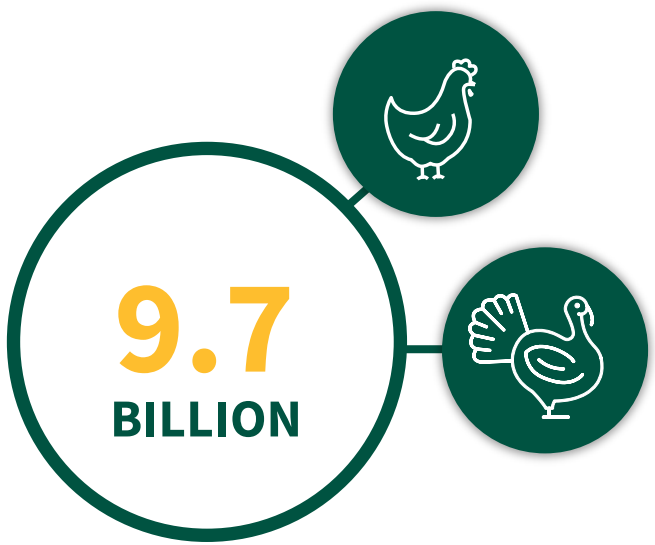
Everyone’s food is safe.

Our Inspection by the Numbers



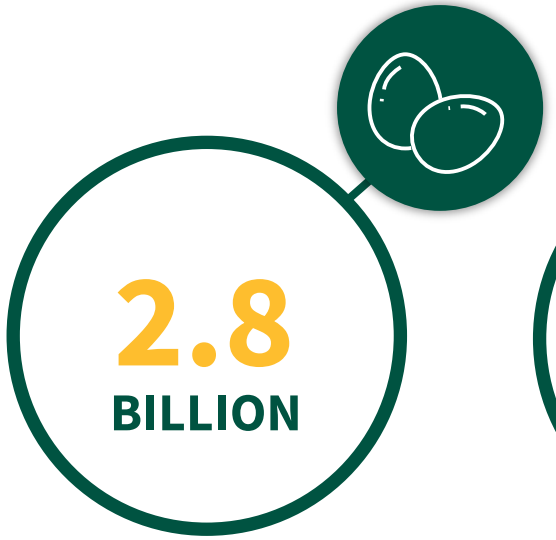
162
MILLION

HEAD OF LIVESTOCK INSPECTED



9.7
BILLION

POULTRY CARCASSES INSPECTED



2.8
BILLION

POUNDS OF LIQUID, FROZEN AND DRIED EGG PRODUCTS INSPECTED

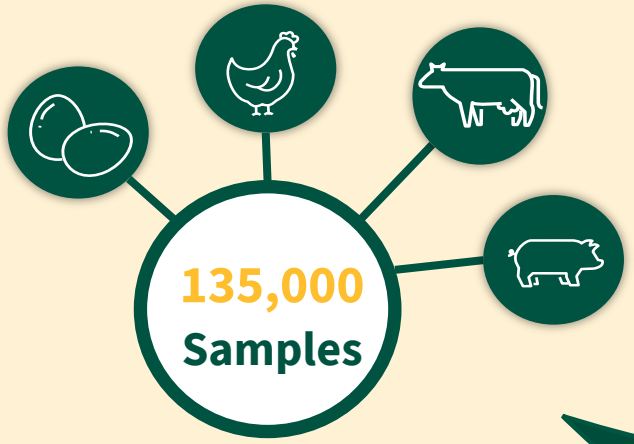
7.6
MILLION

FOOD SAFETY PROCEDURES

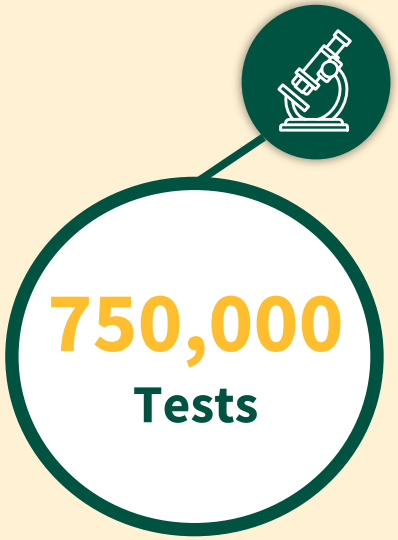
Advancing Food Safety and Inspection

FSIS is a data-driven agency that leads with science to advance food safety while continuing to conduct inspection at all meat, poultry, and egg products establishments.

FSIS Conducts Robust Product Sampling



In FY 2022, the FSIS Field Service Laboratories analyzed over 135,000 samples



These samples were used to perform upwards of 750,000 tests

More than 2,300,000 results were reported

Sampling Programs

FSIS conducts sampling to verify food safety

- To respond to public health concerns and foodborne illness outbreaks
- To verify product meets regulatory requirements
- To verify the adequacy of a HACCP system

FSIS uses sampling programs to

- Make data-driven decisions to improve public health
- Inform Agency decisions
- Refine policy

Role of FSIS Offices in Risk Analysis

- Office of Public Health Science (OPHS):
  - The Risk Assessment and Analytics Staff (RAAS)
  - The Applied Epidemiology Staff (AES)
  - The Microbiological and Chemical Hazards Staff (MCHS)
  - Three Field Laboratories

- Office of Policy and Program Development (OPPD)
  - Identifies risk management options
  - Conducts cost-benefit analyses

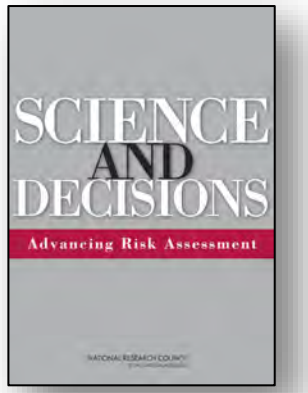
- Office of Field Operations (OFO)
  - Collects inspection and sampling data

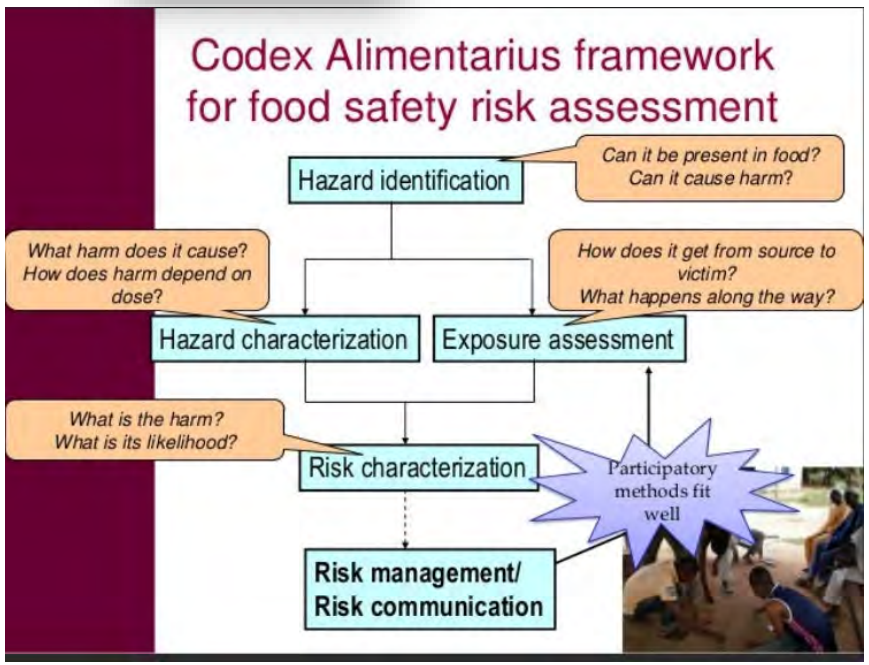
Risk Analysis

- Cornerstone of national and international food safety programs
  - Data-driven, science-led food safety decisions
    - How many *Salmonella* illnesses might be avoided by implementing different performance standards?
  - Increased transparency and stakeholder involvement
- Powerful public health tool
  - Integrates a wide variety of scientific data and information

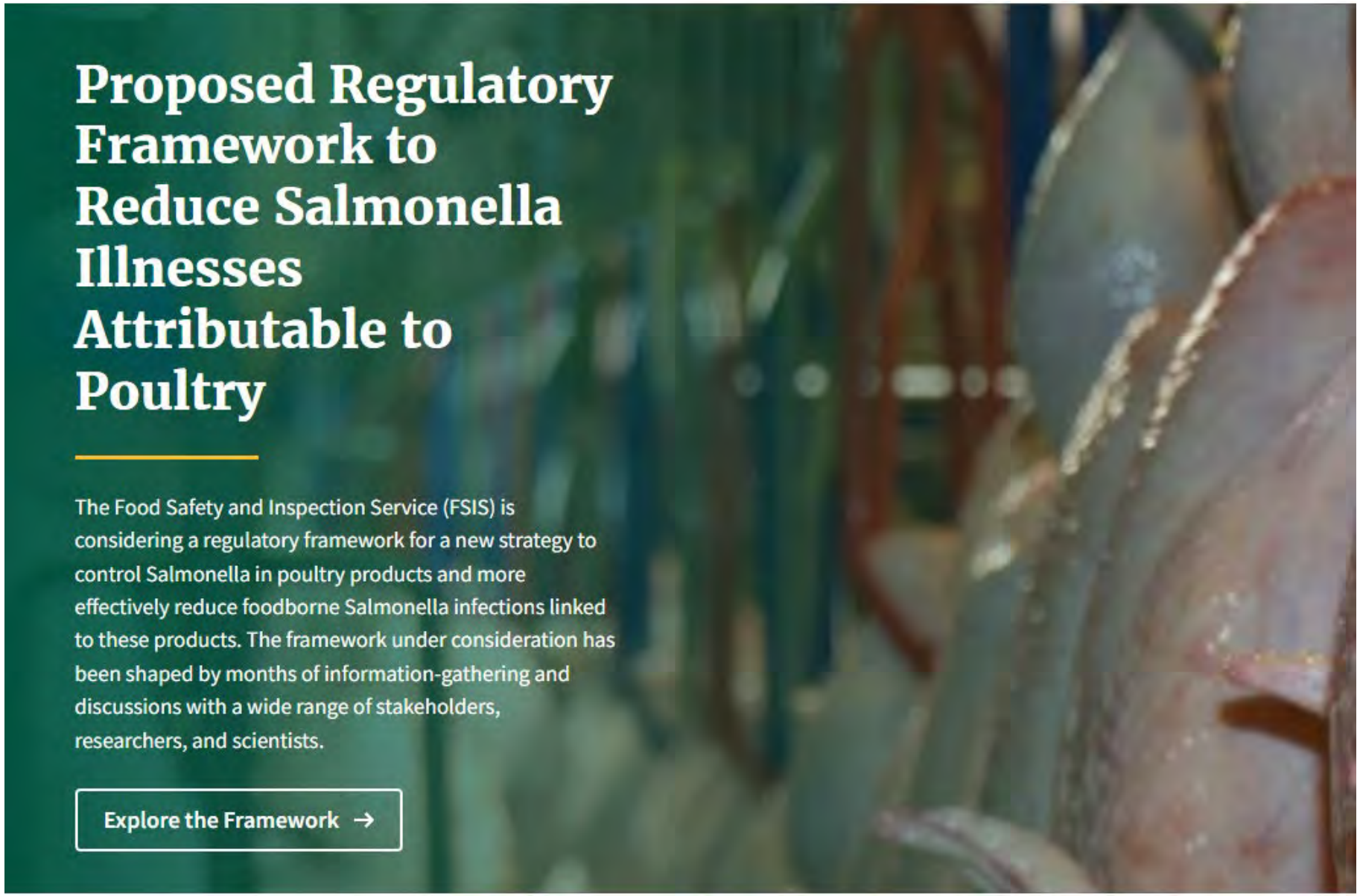
Risk Assessment

- Required for decision-making
  - Executive Order 12866
  - 1994 Reorganization Act for Agriculture (P.L. 103-354)
  - World Trade Organization, Sanitary and Phytosanitary Agreement (Article 5.1)
- Decision-support tool
  - Compare effectiveness of interventions
  - Optimize inspection to mitigate the greatest risk
  - Evaluate standards to achieve food safety objectives
- Design is “fit for purpose”
  - Components consistent with the Codex framework
  - Structure and complexity needed to address specific risk management questions
  - Process follows national guidelines and requirements
    - Office of Management and Budget information quality guidelines to ensure credibility and transparency



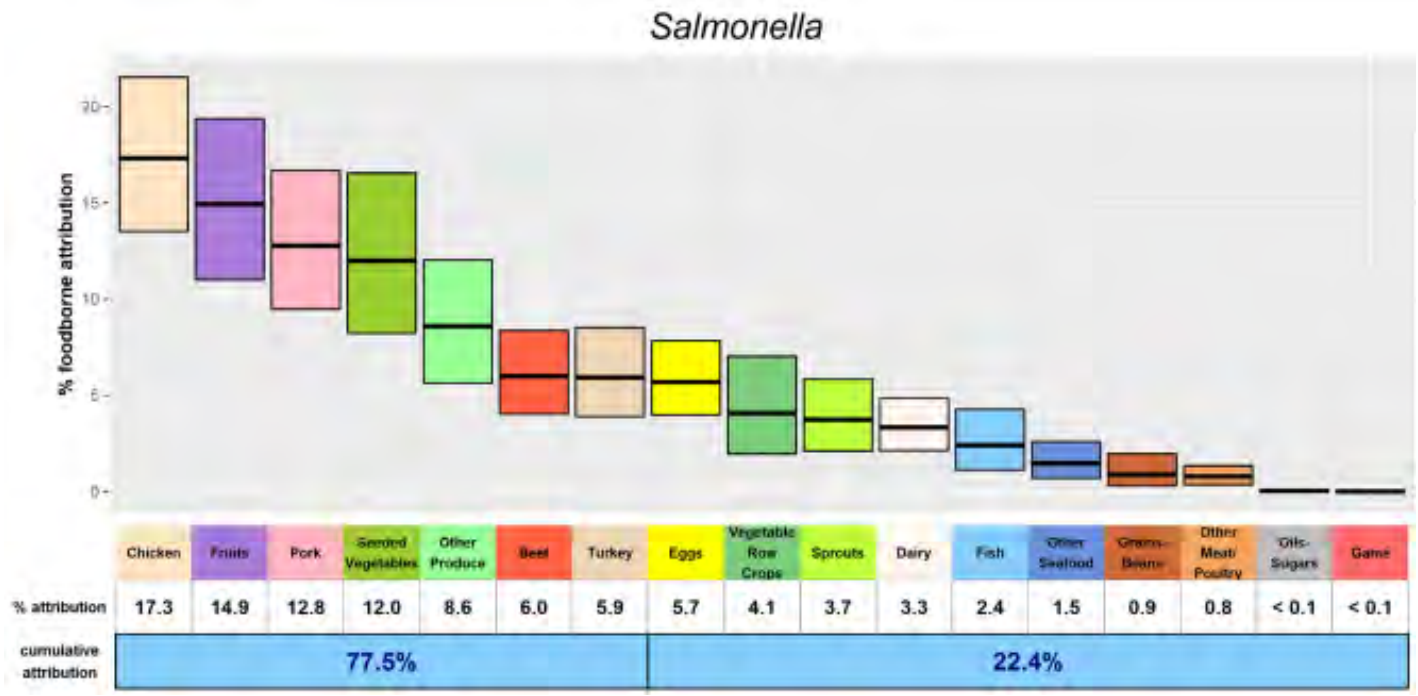


How does FSIS reduce foodborne *Salmonella* illnesses?



Meat, poultry are a leading source of *Salmonella* infections

- ~1 M salmonellosis cases in U.S. annually from all foods (CDC: 2011)
- FSIS-regulated products are recognized as leading sources of *Salmonella* infections.
- The Interagency Food Safety Analytics Collaboration (IFSAC) estimates that 23% of foodborne *Salmonella* illnesses are attributable to poultry consumption — over 17% from chicken and almost 6% from turkey, 12.5% from pork and 6% from beef.

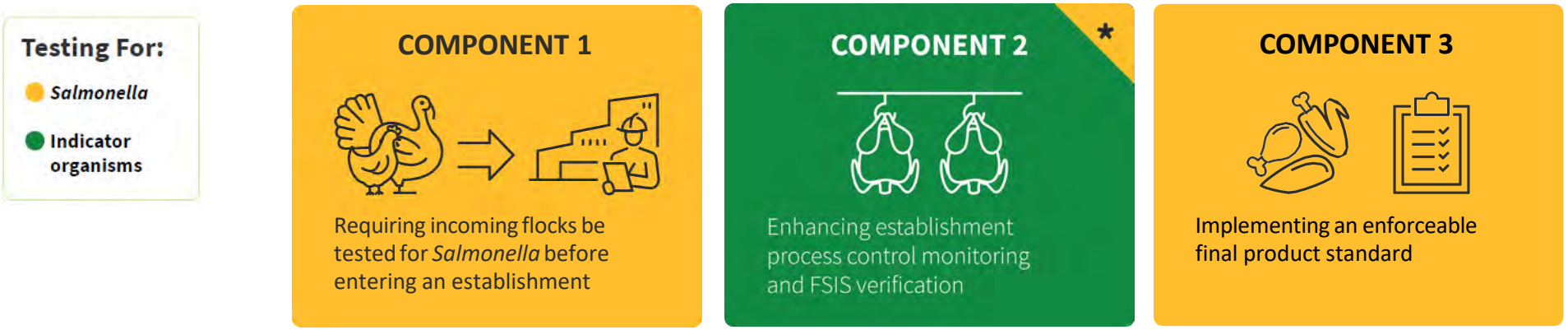


Source: Interagency Food Safety Analytics Collaboration (IFSAC), 2022

Risk Management Framework: Overview

- FSIS is considering three strategies to target *Salmonella* at different points in the slaughter and processing operation (Nov. 3, 2022, Public Meeting)

- These include:
  - Requiring that establishments test for *Salmonella* before entering an establishment.
  - Enhancing establishment process control monitoring and FSIS verification.
  - Implementing an enforceable final product standard.



*Under this proposed framework, testing for Salmonella would also occur during the same steps in production as testing for indicator organisms.

Gathering Scientific Evidence

- National Advisory Committee on Microbiological Criteria for Foods (NACMCF)

- Risk Profile for pathogenic *Salmonella* subtypes in poultry

- Risk Assessments
  - *Salmonella* in chicken
  - *Salmonella* in turkey

- Expanded Exploratory Sampling Enumeration

Quantitative Microbial Risk Assessments of *Salmonella* in Poultry

- Quantitative probabilistic food safety risk assessments
  - Chicken and Turkey: Carcasses, Parts, and Comminuted

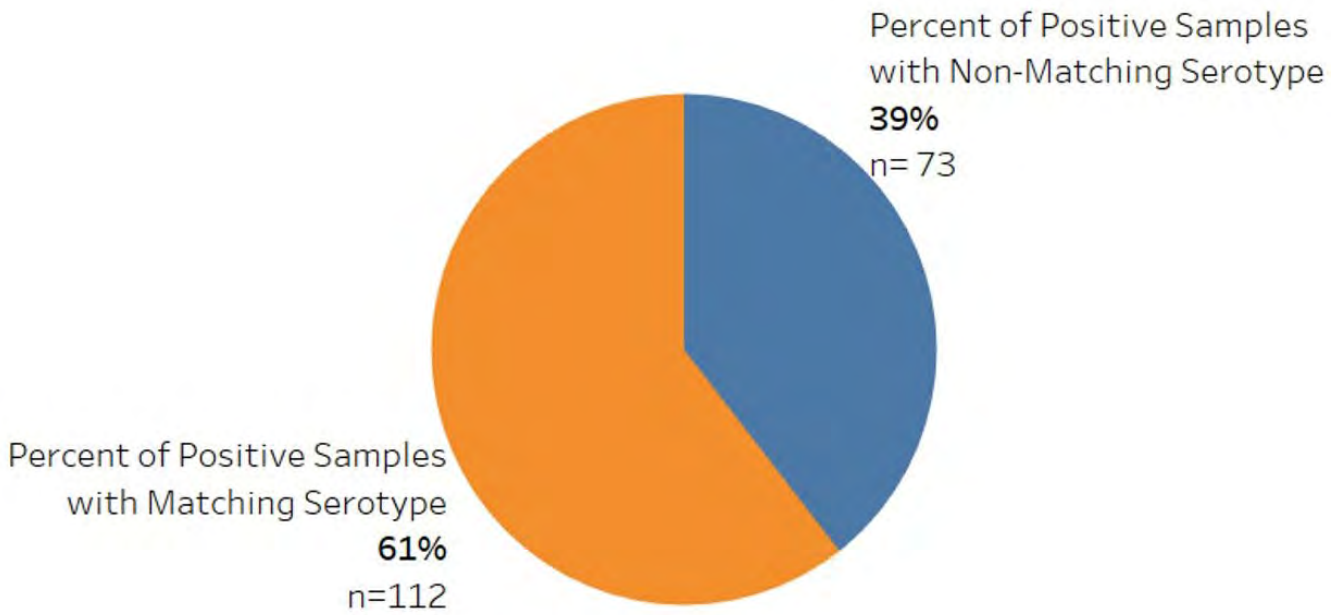
- Decision-support tool to evaluate the public health impact of risk management options for control of *Salmonella* on chicken products.

- FSIS risk assessments supported by Cooperative Agreement:
  - University of Maryland (UMD) data sharing
    - Stakeholder meetings with Industry partners to discuss 1) Data Criteria and 2) Legal Aspects.
    - Continued discussion of data elements to ensure data quality.
  - EpiX Analytics Dose-Response
    - FSIS' upfront commitment to WGS data has made a new QMRA approach possible.
    - Use of innovative tools to group *Salmonella* serotypes by virulence.

Exploratory *Salmonella* Sampling – Rehang vs Post-Chill Serotypes

3.7% (n= 185) of paired samples were positive at both rehang and post-chill

Serotypes detected:



Serotype Distribution among Samples with Matching Serotypes

Kentucky	61%
Infantis	20%
Typhimurium	8%
Enteritidis	5%
Schwarzengrund	3%
Anatum	1%
Blockley	1%
I 7:r:-	1%
Thompson	1%
Grand Total	100%

Rulemaking

- On April 25th, 2023, FSIS announced a proposed notice of determination to declare *Salmonella* an adulterant in not-ready-to-eat breaded and stuffed chicken products.

- In the coming year, FSIS also intends to announce additional proposed rules and policies for implementing this framework.

Quantitative Risk Assessment: *Salmonella*

Evaluate Controls

- Risk Assessment for *Salmonella* in Hatchery Eggs (2020)
- Risk Assessment for Lethality Standards for Ready-to-Eat Meat and Poultry Products (2007)
- Risk Assessment for *Salmonella* in Shell Eggs and Egg Products (2005)

Optimize Inspection

- Risk Assessment for Market Hog Slaughter (2019)
- Risk Assessment for Inspection of Siluriformes Fish (2015)
- Risk Assessment for Poultry Slaughter Inspection (2014)

Inform Standards

- Risk Assessments to Inform Product Standards:
  - Chicken (2022)
  - Turkey (2022)
- Risk Assessments to Inform Performance Standards:
  - Poultry (2015)
  - Pork (2018)
  - Beef (2019)

Webpage: https://www.fsis.usda.gov/science-data/risk-assessments

Communication, Outreach, and Collaboration

- Robust risk assessment webpage that highlights the wide variety of high quality, accessible and transparent QMRAs conducted by FSIS.
- Extensive listing of peer reviewed publications.
- Presentations to stakeholders and academic partners
- Ongoing collaborations with wide variety of partners
  - Government partners
    - Interagency Risk Assessment Consortium (IRAC)
    - Interagency Food Safety Analytics Collaboration (IFSAC)
    - USDA Agricultural Research Service (ARS)
  - External partners
    - UMD
    - EpiX Analytics

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U.S. DEPARTMENT OF AGRICULTURE

Thank you!

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SPEAKER

Prioritization of Food Safety Risks and Decision Making

Juliana Ruzante, PhD

Senior Food Safety and Public Health Scientist
RTI International

Prioritization of Food Safety Risks and Decision Making

June 7, 2023

Juliana M. Ruzante, DVM, MPVM, PhD

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Food Safety Risk Analysis

Source: FAO

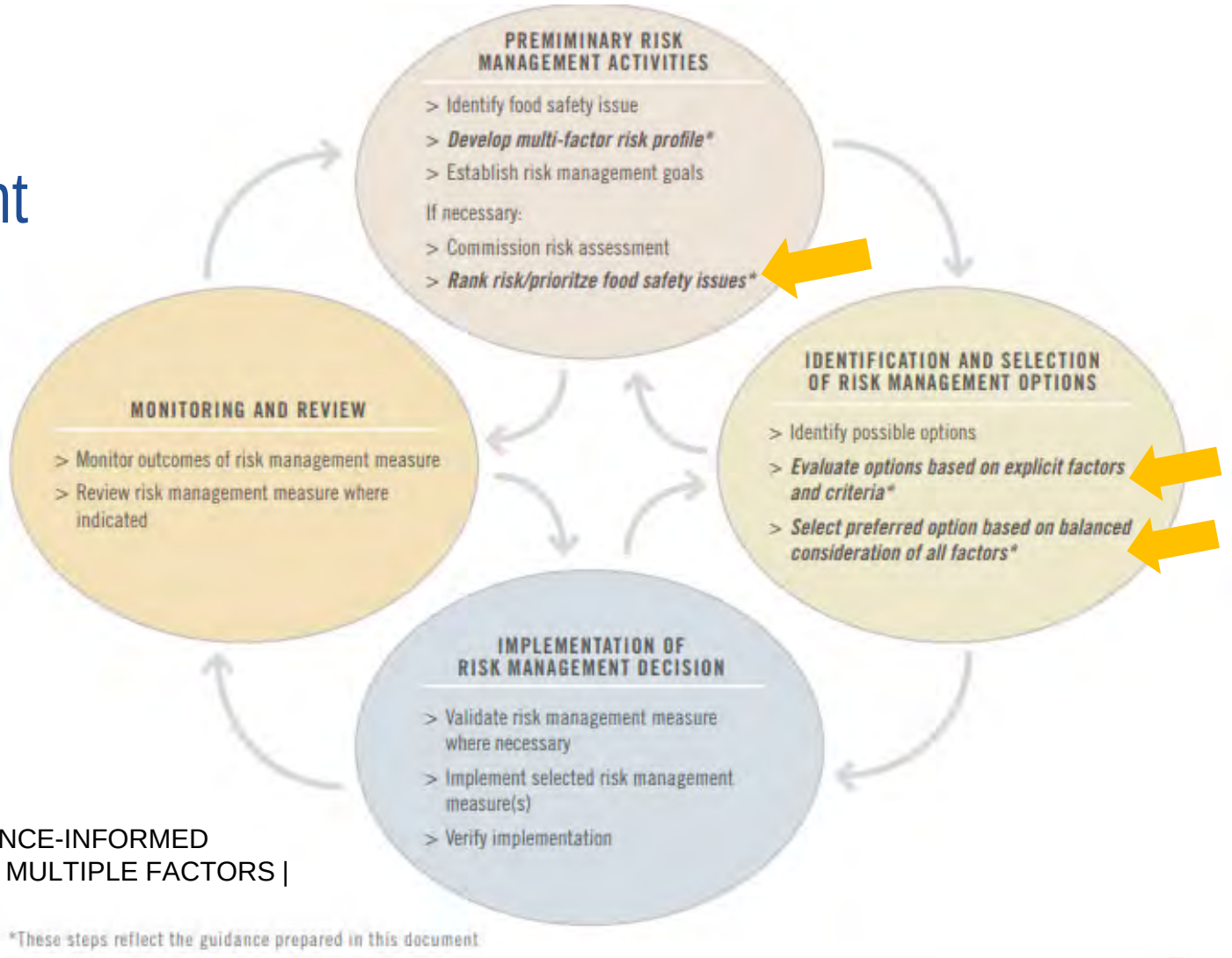
Risk Management

- Risk Management decisions are complex and multi-factorial process

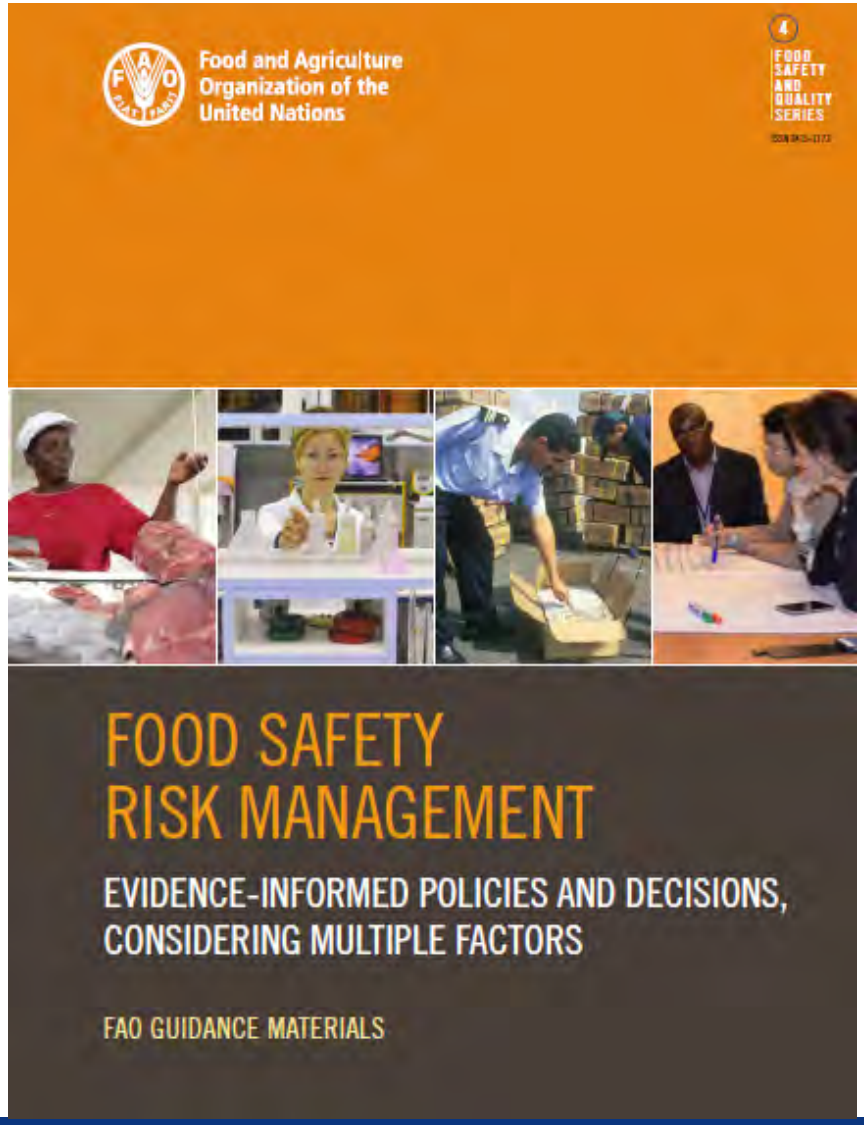
- Need for sound choices to address public health risks in light of economic, social, environmental, and political impacts

“ The technical view is the primary one for decision-making, but risk managers also apply psychological and sociological risk perspectives, as appropriate, in establishing food safety standards.” (FAO/WHO, 2006)

Generic Framework for Risk Management (FAO/WHO)



FOOD SAFETY RISK MANAGEMENT EVIDENCE-INFORMED POLICIES AND DECISIONS, CONSIDERING MULTIPLE FACTORS | https://www.fao.org/3/i8240en/I8240EN.pdf



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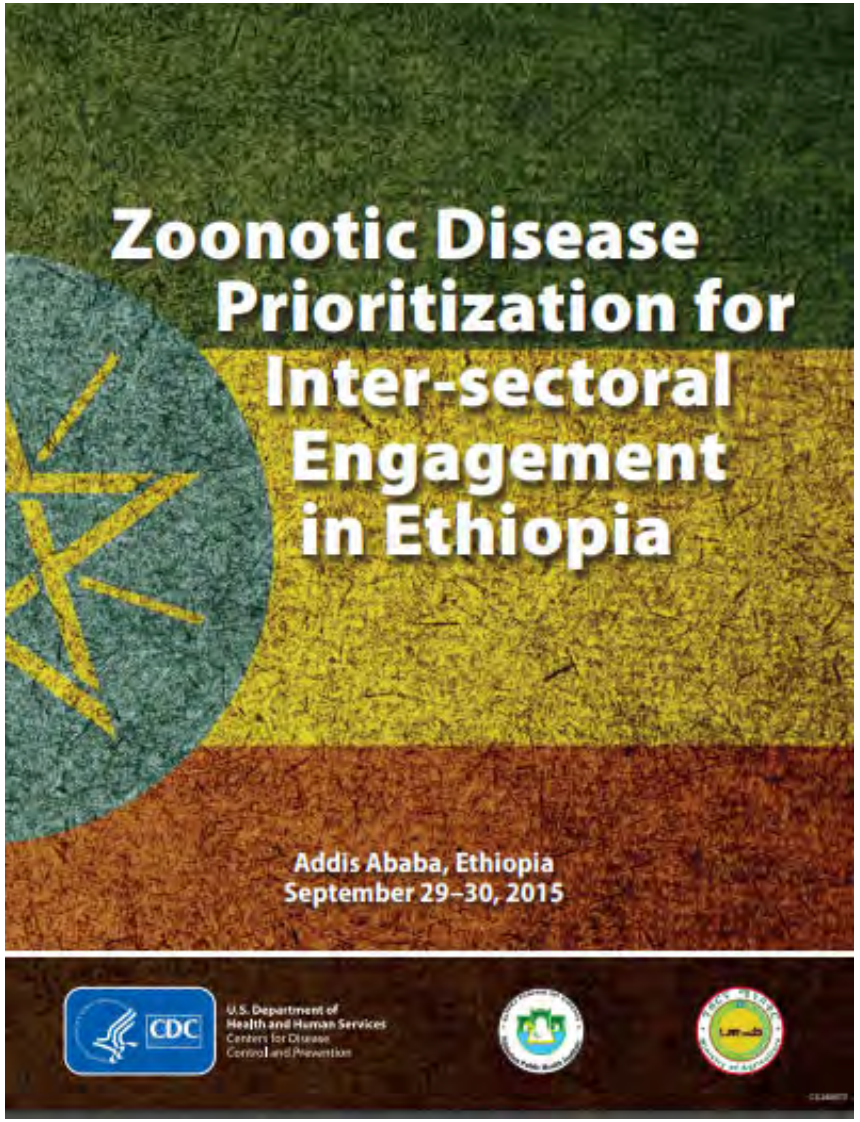
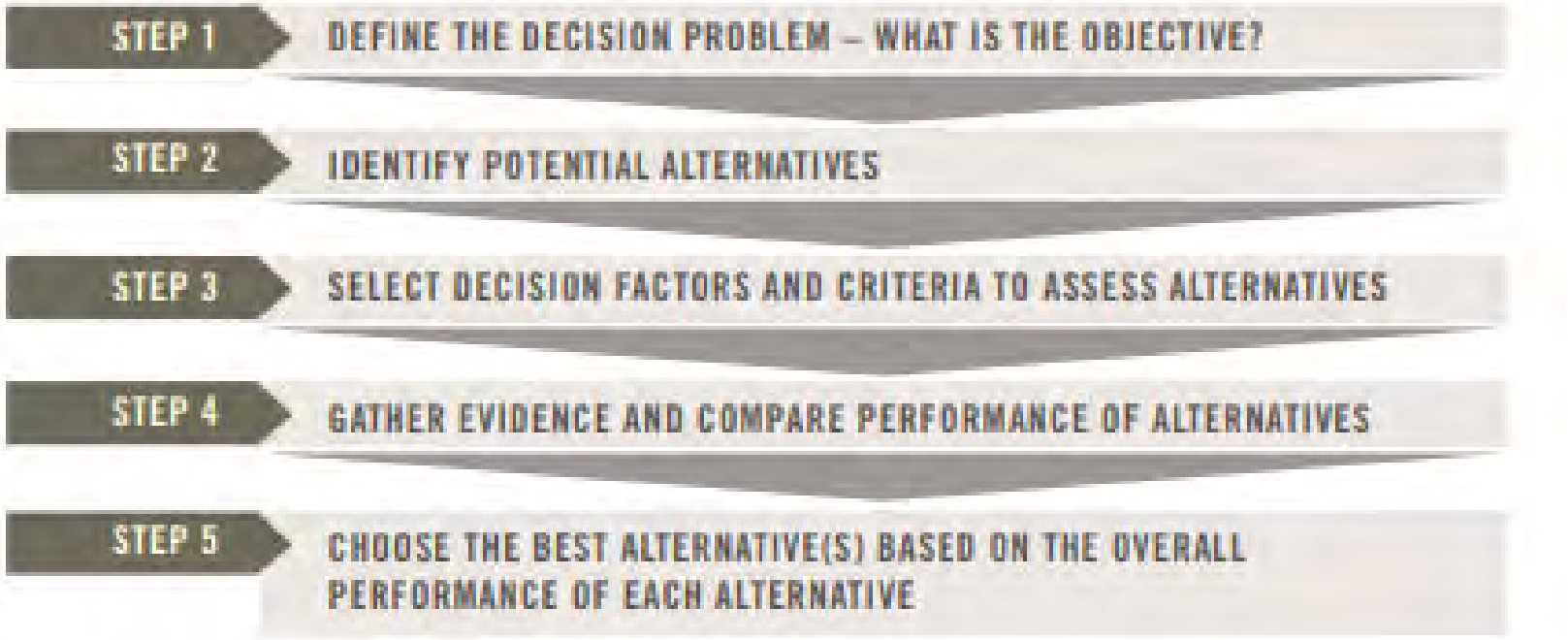


https://www.cdc.gov/onehealth/pdfs/hammett-ethiopi-workshop-508.pdf

5 STEP Process for Multi-factor Decision-Making



http://www.fao.org/3/i8240en/I8240EN.pdf

STEP 1: Define the Decision Problem

- What is that you are trying to address/answer?
  - Prioritize interventions to control a specific hazard/food combination (e.g.: aflatoxin in maize, mercury in fish)
  - Prioritize food safety issues

STEP 2: Identify Potential Alternatives

- Example alternatives for food safety issues:
    1. Brucellosis in milk products
    2. Methanol in unregulated gin
    3. Aflatoxin in maize
    4. Cysticercosis in pork

STEP 3: Select the Decision Criteria

- What factors/criteria are relevant for the decision?
  - Public Health
  - Economic impact
  - Food security
  - Impact on food trade at local, regional, and national levels
  - Environmental concerns
  - Consumer's perception
  - Social, cultural, and ethical considerations
- How to quantify those criteria (e.g.: define the attributes)
  - What will be the performance indicator for the criterion (e.g.: metric)
  - Data available for quantitative quantification?

Example

Criterion	Performance indicator/metric	Source
Public Health	Disability adjusted life years (DALYs)	Systematic/scoping review (Annex 1) and published DALY data
International trade	Export value in USD billions/year	FAOSTAT Trade data
Consumer perception	Normalized scale between 0 (=low risk/ high acceptance) and 1 (=high risk/low acceptance)	Expert elicitation or focus groups

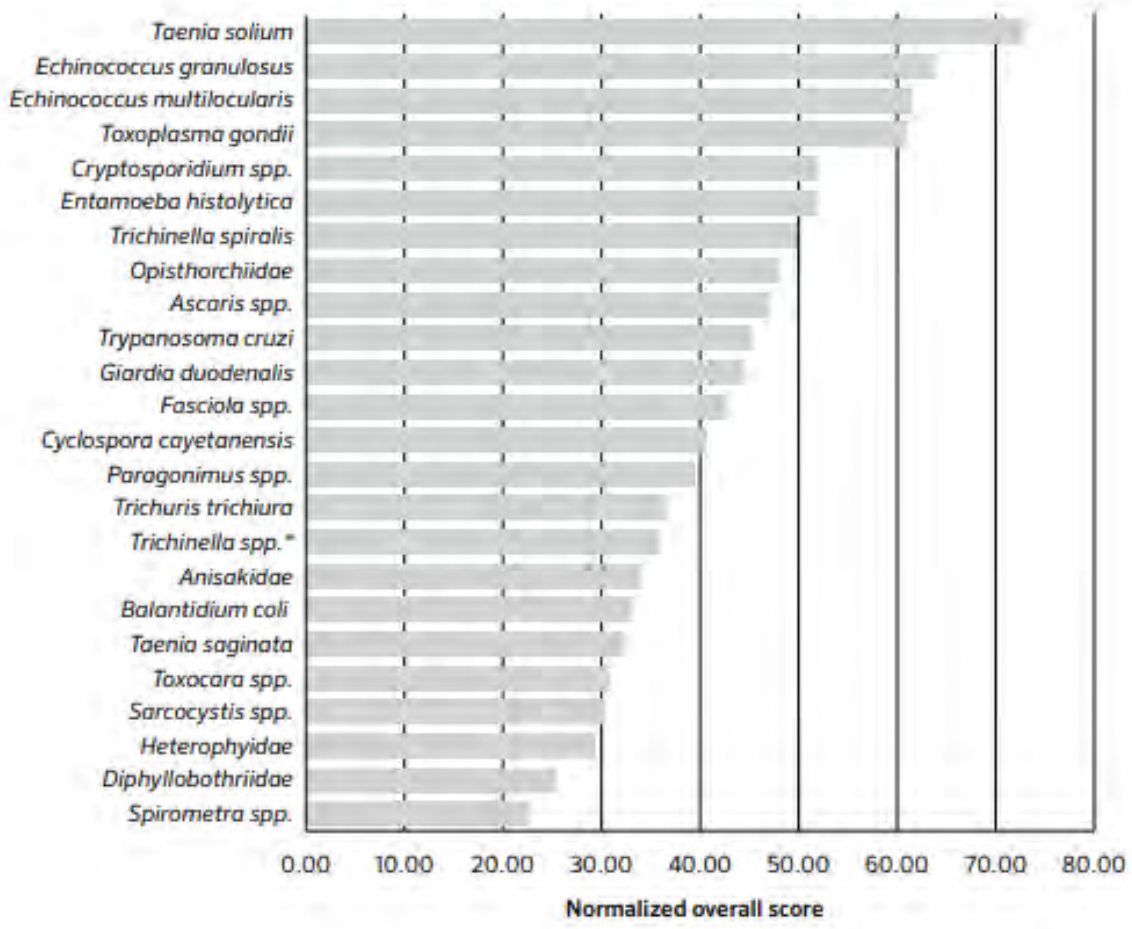
Step 4: Gather Evidence and Compare Alternatives

- Example performance matrix

Alternatives	CRITERIA		
	Public Health	**Market**	**Consumer Perception**
	DALY (years)	(million CAN$)	
Campylobacter/chicken	808	5,472	0.3
Salmonella/chicken	449	5,472	0.25
Salmonella/spinach	1	118	0.5
E. coli O157/spinach	3	118	0.8
E. coli O157/beef	260	5,264	0.6
L.monocytogenes/RTEmeats	58	974	0.6

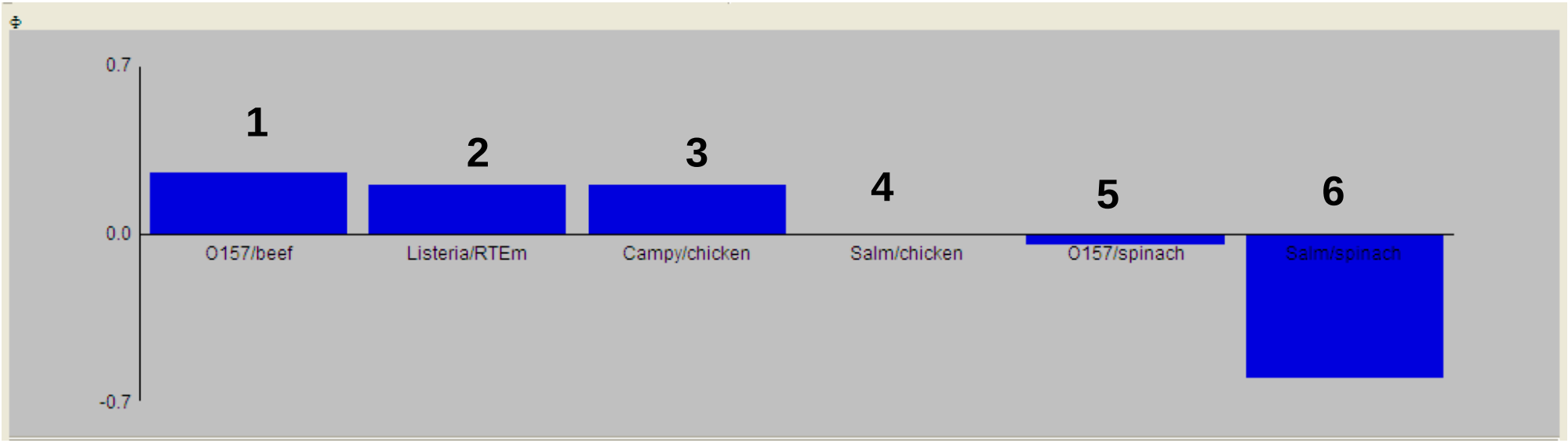
Step 5: Choose the Best Alternative

- Aggregate the results/scores to produce the prioritization
  - Linear additive models (e.g. average performance scores across all criteria).
  - Outranking methods



https://apps.who.int/iris/bitstream/handle/10665/112672/9789241564700_eng.pdf?sequence=1&isAllowed=y

Step 5: Choose the Best Alternative: Outranking example



Final Considerations

- Any risk ranking/prioritization efforts is data intense. Data gaps not addressed adequately will generate unreliable outcomes
  - Uncertainty and sensitivity analysis were not discussed here but are important and should be considered
  - Qualitative approaches can be a start but will not address data gaps
- In practice, risk prioritization is done based on multiple factors—not only public health
- Formally incorporating all factors into prioritization efforts will result in more rigorous and transparent decision making

Thank you

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Introduction to Risk-Based Approaches in Food Safety

Panel Discussion

Joanna Zablotsky-Kufel

Juliana Ruzante

Arie Havelaar

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Applying Risk-Based Approaches in Food Safety

June 14, 9 AM EDT

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A link to the recording and presentations will be emailed to attendees

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