# Considering Risk Management for Complex Systems

Peg Coleman, Microbiologist/Risk Analyst
Coleman Scientific Consulting
colemanmellen@gmail.com

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# Outline

1. Some History and Evolution of Risk Management Practice

2. Relevant SRA Specialty Groups and Fundamental Principles

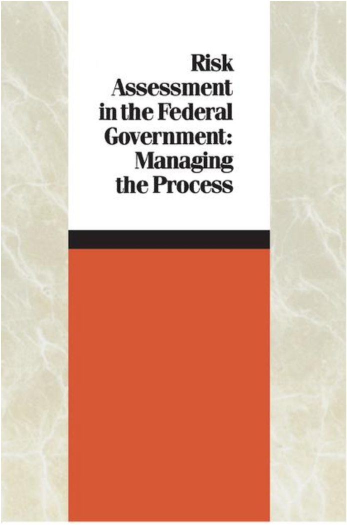
3. Nine Manuscripts Extending Risk Management Model Structure

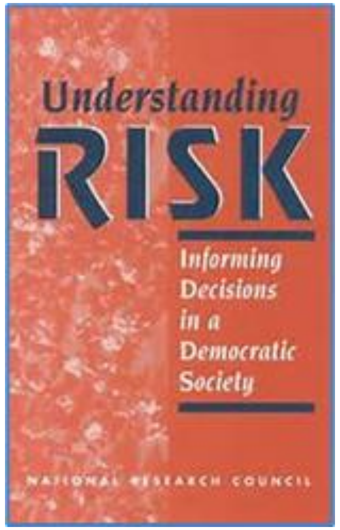
4. Standardization for Evaluating and Managing Complex Systems: RAQT

# 1. Some History and Evolution of Risk Management Practice

# Evolution: Initial Linear Risk Analysis Process with Separation of Management to more Complex Interdependent Processes

- Covello and Mumpower, 1985, Risk Analysis and Risk Management: An Historical Perspective
  - Introduced methods for establishing causality, quarantines for Black Death of 1300s and leprosy, vaccination for smallpox
- **National Academy of Sciences**, the National Academies Press. Two historical reports (1983; 1996) and many others available free for downloading at http://www.nap.edu/)
  - Introduced analytic-deliberative process, with transparent cycles of analysis and deliberation, ideally with open discourse including all stakeholders interested in risk analysis decisions
- **Society for Risk Analysis (SRA**; https://www.sra.org/)
  - Founded in 1980 with interdisciplinary vision
  - Global membership between 1 and 2 thousand risk practitioners
  - Publishes journal *Risk Analysis*
  - Offers webinars and podcasts (free)



# Society for Risk Analysis (SRA)
## Risk Management and Governance Core Subject

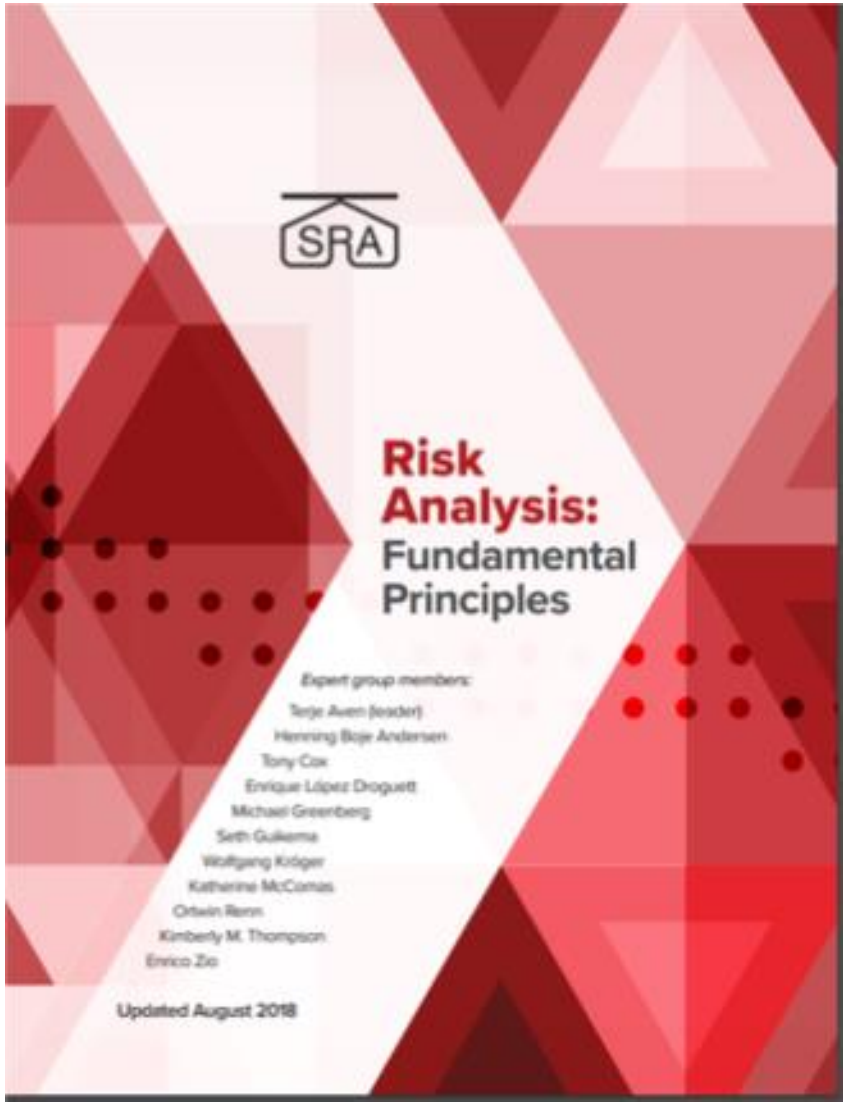
- Covers measures and activities carried out to manage and govern risk, **balancing** developments and exploring opportunities on the one hand,
  and avoiding losses, accidents and disasters on the other

- Main emphasis on providing insights and guidance on multi-dimensional, multi-actor, multi-institutional **decision and policy making** and on resolving emerging **trade-offs**

- Some topics: acceptance and tolerability, analytic-deliberative process, avoidance, benefit-risk, cost-benefit, optimization, reduction, resilience, retention robustness, sharing, trade-offs, transfer

# SRA Risk Analysis Fundamental Principles: Risk Management

- **Risk management** covers all measures and activities carried out to manage and govern risk, balancing developments and exploring opportunities on the one hand, and avoiding losses, accidents and disasters on the other.
- In general, the proper risk level is a result of a **value** and **evidence/knowledge-informed process**, balancing different concerns.
- To generate **value**, **risk taking** is needed, dependent on context, values, weighting.



# QMRA and Risk Management

- **QMRA** processes build in **Risk Management** exploring **scenarios for alternative actions** that might reduce risk or increase benefit

- Difficulties or **constraints** of Risk Management
  - Tendency for maintaining status quo, 'regulatory backfill' rather than independent evidence-based analysis using best available data and alternatives to conservative assumptions that overestimate risk and introduce bias
  - Values and beliefs may override evidence
  - Data inconsistent with values or beliefs may be excluded or dismissed, introducing bias into QMRA

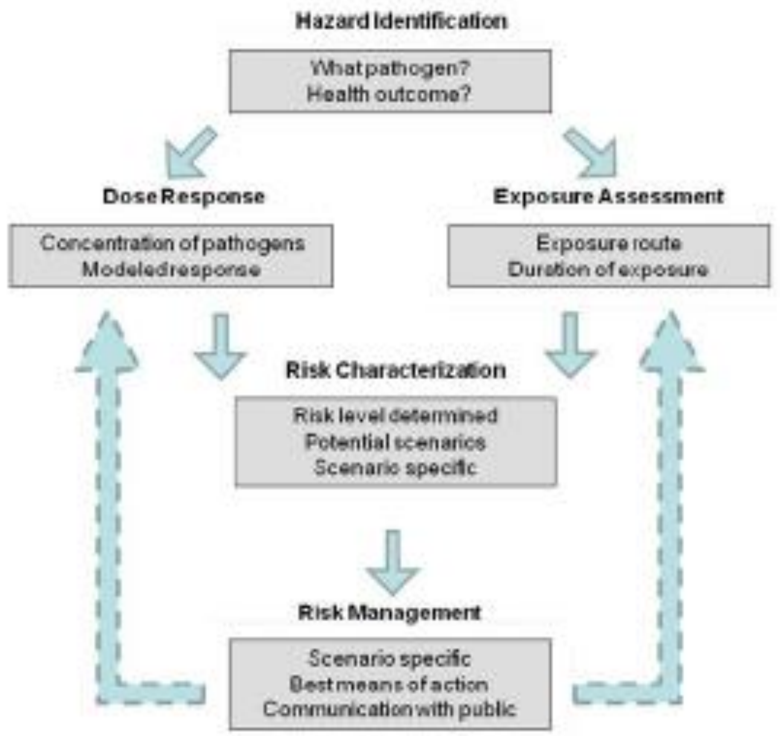



Figure 2: QMRA follows specific steps

# Connecting Risk Management and Policy with SRA 2022 Theme

- Consider some global risks and tipping points for quality risk analysis that might identify favorable benefit-risk outcome for decisions
- Consider risk management and policy making as a '**value proposition problem**':
  - How might we identify tipping points to increase value in complex systems?
- **TWO GIVENs**
  1. strongly held ideology/beliefs may not be influenced by scientific evidence
  2. policy making = *f* (science, ideology, politics, …)

SRA 2022
Global Risks @ the Tipping Point
Risk Analysis & Policy Driving Systemic Change
December 4-8 • Tampa, Florida

**How might risk analysts facilitate processes for distinguishing ideology and politics from science?**
**How might risk analysts promote shifting the balance toward evidence-based decisions and systemic change?**

# 2. Relevant SRA Specialty Groups and Fundamental Principles

# SRA Specialty Groups with Specific Focus on Risk Management

- **Applied Risk Management** (~300 members)
  - Focuses on translating risk analysis into action
  - Relevant Scientific Literature Registry
  - Risk Analysis Quality Test (RAQT)
- **Decision Analysis and Risk** (~430 members)
  - Focuses on promoting the use of risk- and decision-analysis tools in supporting decisions
- **Risk Policy and Law** (~100 members)
  - Focuses on support collaborative research and dialogue to identify and illuminate issues that arise from risk-related legislative acts, regulatory rules, treaties, oversight and review mechanisms, judicial proceedings, and other legal institutions

# SRA Risk Analysis Fundamental Principles:
## Risk Management and Governance

- **Risk governance** is the application of governance principles to the identification, assessment, management and communication of risk. Concerned with how relevant risk information is collected, analysed and communicated and management/regulatory decisions are taken.

- A **mixture** of three major strategies generally advised:
  (I) risk-informed strategies
  (II) cautionary/precautionary/robustness/resilience strategies (meeting uncertainties)
  (III) discursive strategies (for discourses exploring ambiguity and values)

- Process of **balancing different concerns** can be supported by **cost-benefit** methods in addition to **broader judgements of risk and uncertainties**, as well as **stakeholder** involvement processes

# 3. Nine Manuscripts Extending Risk Management Model Structure

# A. Considering Culture and Economics:

## Simple Solution Decreased Risk of Cholera

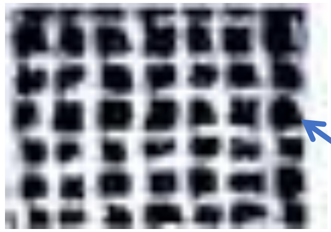
(Colwell et al., 2003; Huq et al., 2005)

**Source:** drinking contaminated river water

**Simple Solution** in **Bangladesh** (2000):

Rita Colwell & Anwar Huq trained villagers to filter river water with common **cloth** (sari cloth)

- Removed copepods that **concentrate** bacteria to **high doses**
- Scientific knowledge of **ecological link** of **copepods** and **cholera outbreaks** informed solution



cloth filters **copopods**, NOT *Vibrio* bacteria

# B. Risk Management for Development –
## Assessing Obstacles and Prioritizing Action

(Hallegatte and Rentschler, 2015, *Risk Analysis* 35(2))

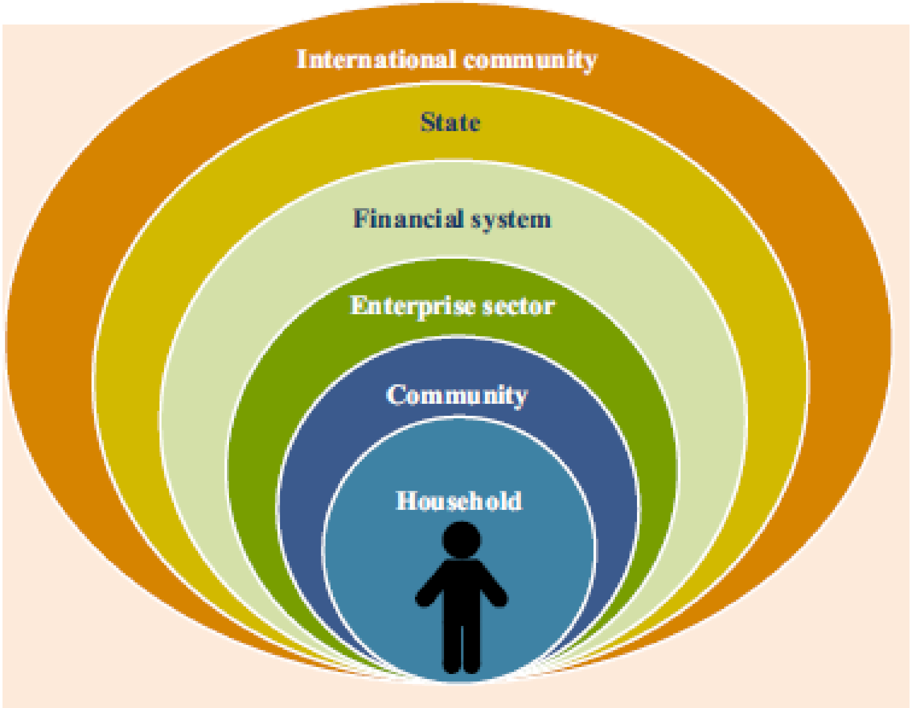



**Fig. 2.** Individuals are embedded in their wider socioeconomic environment. Risk management measures need to be coordinated across these levels.
*Source*: WDR 2014.

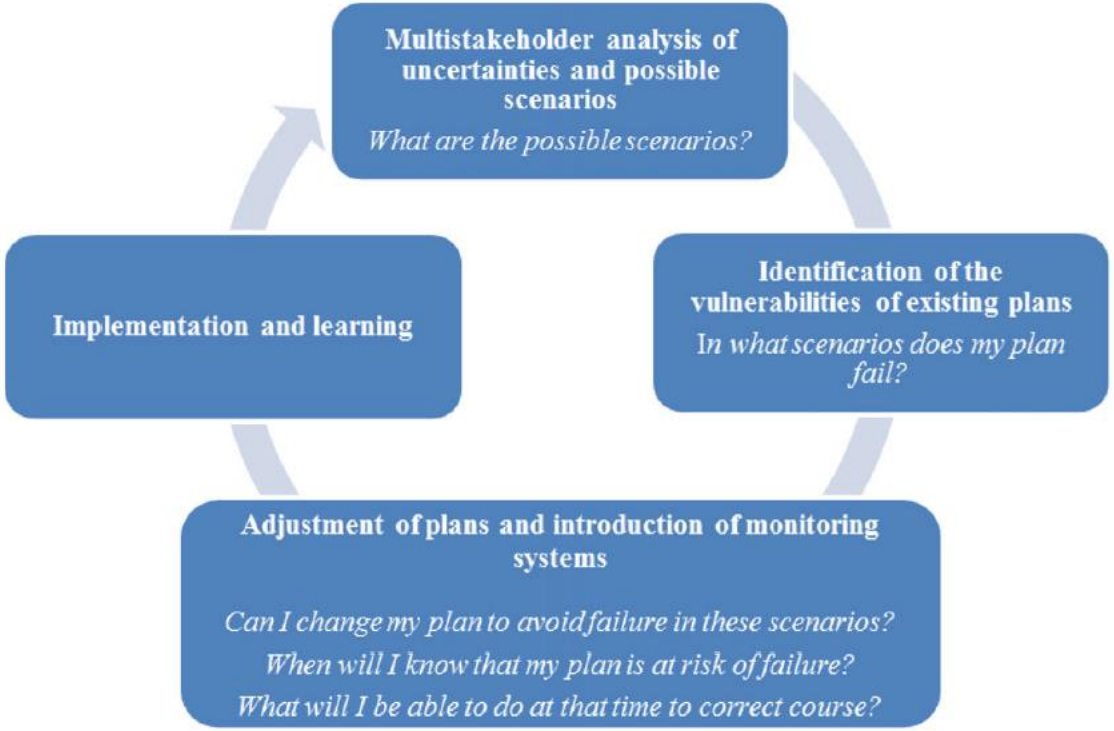



**Fig. 6.** An iterative process of decision making to prompt robust action in the face of uncertainty.
*Source*: WDR 2014.

**Section 4.3. Choose Flexible Solutions and Build in Learning**

To cope with uncertainty and differences in beliefs, values, and sensitivity, policymakers should aim for robust policies that may not be optimal in the most likely future, but that lead to acceptable outcomes in a large range of scenarios and for a large range of stakeholders."

# C. Risk Management and the Wisdom of Aldo Leopold

(Warren and Kieffer, 2010, *Risk Analysis* 30(2))

## Aldo Leopold

- Ecologist, conservationalist, author of *A Sand County Almanac*
- Biotic or land pyramid of energy circuits, food webs, ecological interdependencies: complex functional interactions of climate and atmosphere, rocks, soils, waters, plants, animals, {microbes}, operating together as an interdependent communities, complex ecosystems
- Warren and Kieffer applied Leopold's body of work as criteria for contemporary risk management

## Criteria of 'Land Health' Motivated by Land Ethic

- Common technology-driven over-consumptive lifestyle in US and other developed countries disconnected from natural systems of planet Earth and possibilities for just, prosperous, enduring, and peaceful global civilizations

## 'Stealth Disasters' Caused or Amplified by Human Activity

- 1930s Great Plains Dust Bowl crisis, combination storms, drought, agriculture methods not attuned to protecting soils in dry windy climate
- Industrialized agricultural monocultures with chronic loss of soil fertility and biodiversity in conventionally plowed, fertilized, and irrigated agricultural systems
- Loss of biodiversity, plants, animals, microbes, … diminishes nature's capacity for self-organization, self-renewal, self-healing, resilience
- Disproportionate impacts to poor, marginalized, undervalued when ecology is too simplistic or rudimentary

## Call for scientists to communicate understanding of natural (and disturbed) systems to conserve land with its biota AND reduce risks to ecosystems, humans and natural environment

- Concern about ecology and risk management from both scientific and cultural or philosophical perspectives
- Avoid diminishing nature's capacity for self-renewal (translation: avoid 'stealth disasters'; promote 'regenerative agriculture')

# D. Alternative Approaches to the Risk Management of *Listeria monocytogenes* in Low Risk Foods

(Farber et al., 2021, *Food Control* 123:107601)

Alternative perspectives on microbiological criteria for foodborne listeriosis

- US FDA: 'zero tolerance' (ZT) for Lm in RTE foods (declared adulterated based solely on pathogen presence using 2-class sampling plan)
- Canada, EU: 100 cfu/g for low risk foods suppressing growth of Lm using more flexible 3-class sampling plan

Multiple studies on thresholds for innate resistance to listeriosis (Buchanan et al., 2017; Rahman et al., 2016, 2018, 2020)

**Key findings:**

- **FDA** (blanket ZT) vs **FSIS** (alternative approaches: Gallagher et al, 2003; 9 CFR Part 430, 68FR34208-34254)
- ZT **very strong disincentive** for industry testing contact surfaces, finished product
- **benefits not recalling low-risk foods** not supporting Lm growth and containing low levels include:
  i) not wasting limited industry and regulator resources;
  ii) not losing consumer confidence,
  iii) maintaining a secure and sufficient food supply,
  iv) decreased food waste,
  v) avoiding negative effects on the environment, and
  vi) avoiding unnecessary costly food recalls
- **Recommendations**
  i) use alternate sampling approaches for low-risk foods;
  ii) use big data to better inform microbial risk assessments;
  iii) perform risk-benefit assessment; and
  iv) develop novel consumer food handling/risk communication strategies

**The application of 'zero tolerance' for Lm appears to reflect ideology, not science.**

# E. Combining Quantitative Risk Assessment of Human Health, Food Waste, and Energy Consumption: The Next Step in the Development of the Food Cold Chain?

(Duret et al., 2019, *Risk Analysis* 39(4):906-925)

- Links prediction of product temperature in refrigeration processes, energy consumption, and predictive microbiology

- A cost-benefit analysis approach (DALYs) and 2 multi-criteria decision analysis methods (Analytic Hierarchy Process and ELECTRE III) used to rank 8 interventions related to human and environmental health, sustainability, and economics

- Utility high where no single '*a priori* optimal' solutions exists AND decision makers must prioritize among diverse criteria to identify 'best compromise'

- Setting refrigerator thermostat at 4°C best compromise between three potentially conflicting objectives
  - Food safety (risk of illness; estimated $50 billion US)
  - Food waste (spoilage, recalls for low-risk foods; estimated $218 billion US)
  - Economic loss (energy for refrigeration, recalls for low-risk foods)

# F. *Salmonella* Prevalence Alone Is Not a Good Indicator of Poultry Food Safety

(Oscar, 2021, *Risk Analysis 41*(1))

**USDA/FSIS regulates raw poultry meat** based on the **genus *Salmonella* alone**, a variable **insufficient to predict safety**

- **Risk of salmonellosis** was **significantly** ($p > 0.05$) affected by:
  - **Prevalence**
  - **Number** in 26 samples collected in 2018
    - *Salmonella* not detectable to 40 bacteria in 25 g ground turkey samples
    - Natural microbiota 25,000 to 250,000,000 bacteria in same samples
  - **Virulence**
  - Incidence and extent of **undercooking**
  - Food **consumption behavior**
  - **Host resistance**

  but was **not affected** by **serving size**, **serving size distribution, or total bacterial load** of ground turkey when all other risk factors held constant

- Prevalence **not correlated** ($r = -0.39$; $p = 0.21$) with salmonellosis risk (other factors not held constant)

- Need for more holistic approach for modeling complex food systems, developing alternative risk management strategies and scenarios, and monitoring relevant predictors of safety

# G. Policy Responses to Foodborne Disease Outbreaks in the US and Germany

(Meagher, 2022. Agriculture and Human Values 39:233–248
https://doi.org/10.1007/s10460-021-10243-9)

## Social construction of pathogenic *E. coli* outbreaks, ABSENT public engagement, deliberation

- **FDA: 2006 leafy greens outbreak** (276 illnesses, 5 deaths)
  - Disregarded evidence of failures at processing facility, framed outbreak as an **agricultural problem**
  - Warned consumers to **avoid eating fresh spinach from any source** even though contaminated product quickly traced to **CA grower**
  - Targeted **farm-level food safety program**, blaming farmers or 'nature', pursuing **technical fixes on farms** rather than **holistic structural reforms** of both **production and processing industries**
  - Unanticipated consequence of actions: interfered with **farm conservation practices**, interventions **too costly for small producers**, furthering **Big Ag 'regime'**, continuing leafy green outbreaks, illnesses, hospitalizations, and deaths (CDC, 2021)

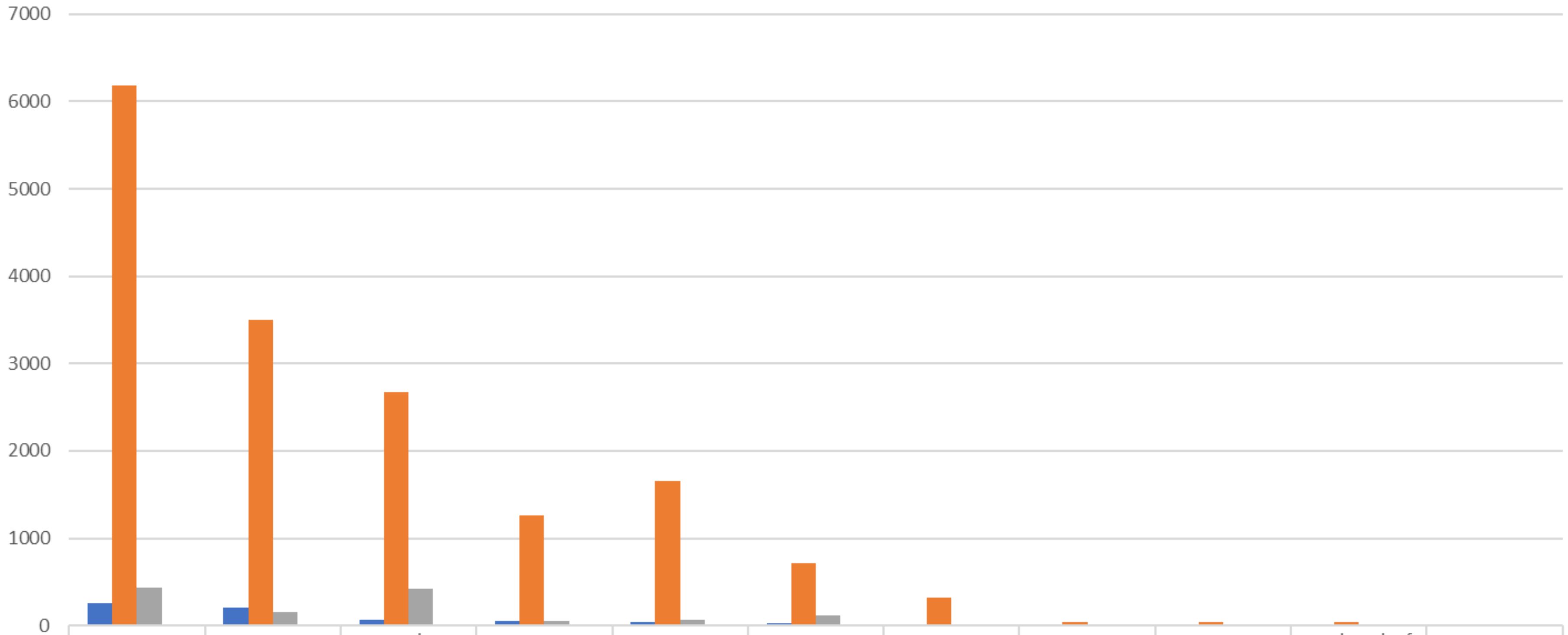
- **Germany: 2011 sprouts outbreak** (~4,000 illnesses, 53 deaths)
  - Blamed 'external' source of seeds, no sprouting facility examination, reducing political pressures for holistic reforms of food chain
  - Framed outbreak as public health problem, pursuing enhanced coordination for public health responses

Table 1 Five alternative policy options

| Policy options | Example actions |
|---|---|
| 1. Consolidate food safety authority | Centralize authority over standard-setting and enforcement in a single agency |
| 2. Abandon risky food products | Substitute less-risky products for bagged greens and raw sprouts |
| 3. Reduce scale or speed of production | Hand-harvest leafy greens; decentralize processing; lower sprouting temperatures |
| 4. Regulate cattle | Treat manure; increase distance between feedlots and produce fields; cull "super-shedder" cattle |
| 5. Do nothing | N/A |

# Reality Check: US Leafy Green Outbreaks by Food Grouping

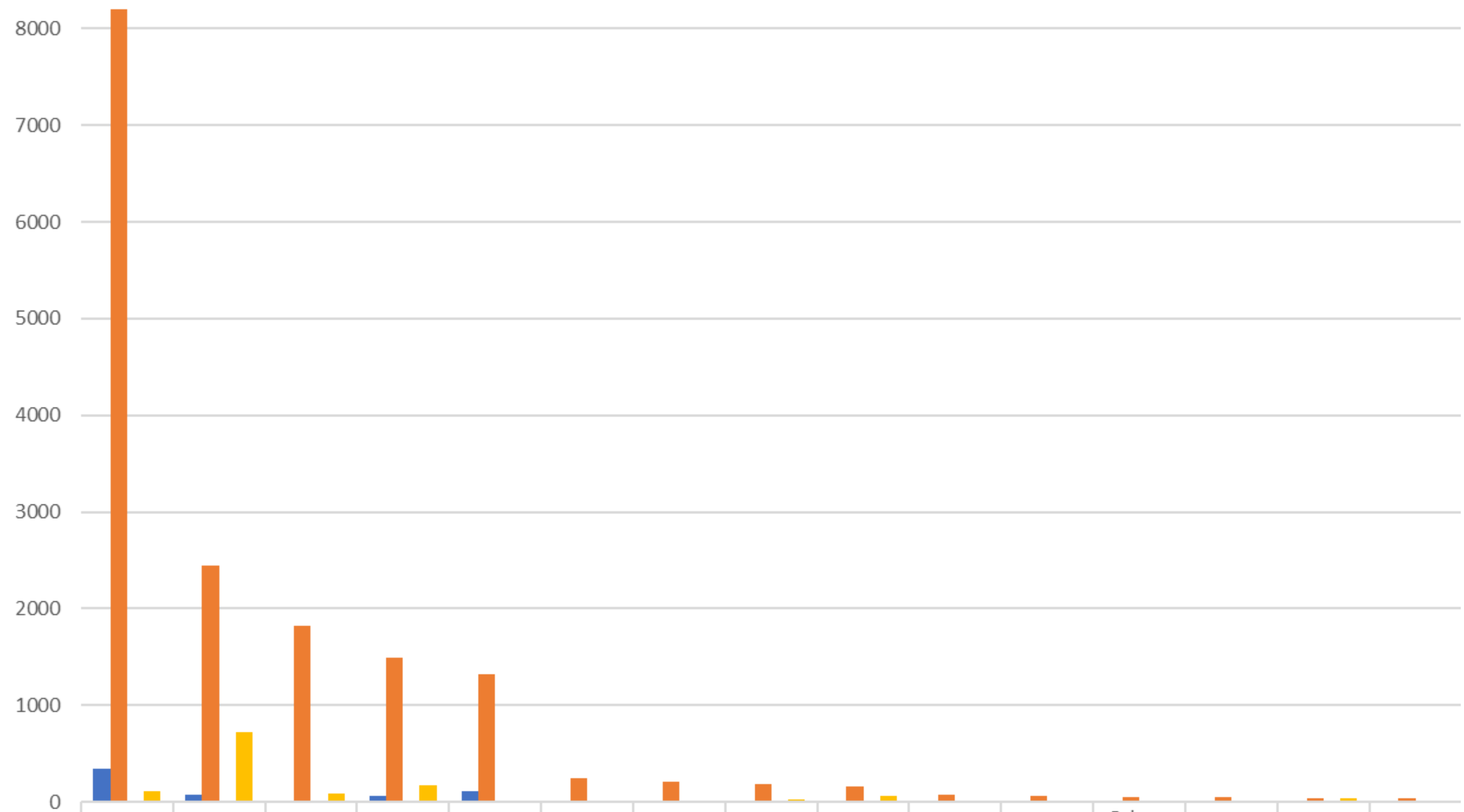
(CDC NORS, 2021; 2005 to 2020)




| | leafy green | lettuce | romaine lettuce | leaf lettuce | cabbage | spinach | green salad | kale | mesclun mix | moringa leaf powder | salad |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Outbreaks | 254 | 206 | 65 | 50 | 41 | 32 | 14 | 5 | 2 | 1 | 1 |
| Illnesses | 6,188 | 3,501 | 2,673 | 1,265 | 1,659 | 712 | 323 | 37 | 37 | 35 | 4 |
| Hospitalizations | 434 | 148 | 417 | 49 | 66 | 119 | 6 | 5 | 0 | 6 | 0 |
| Deaths | 10 | 3 | 5 | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 0 |

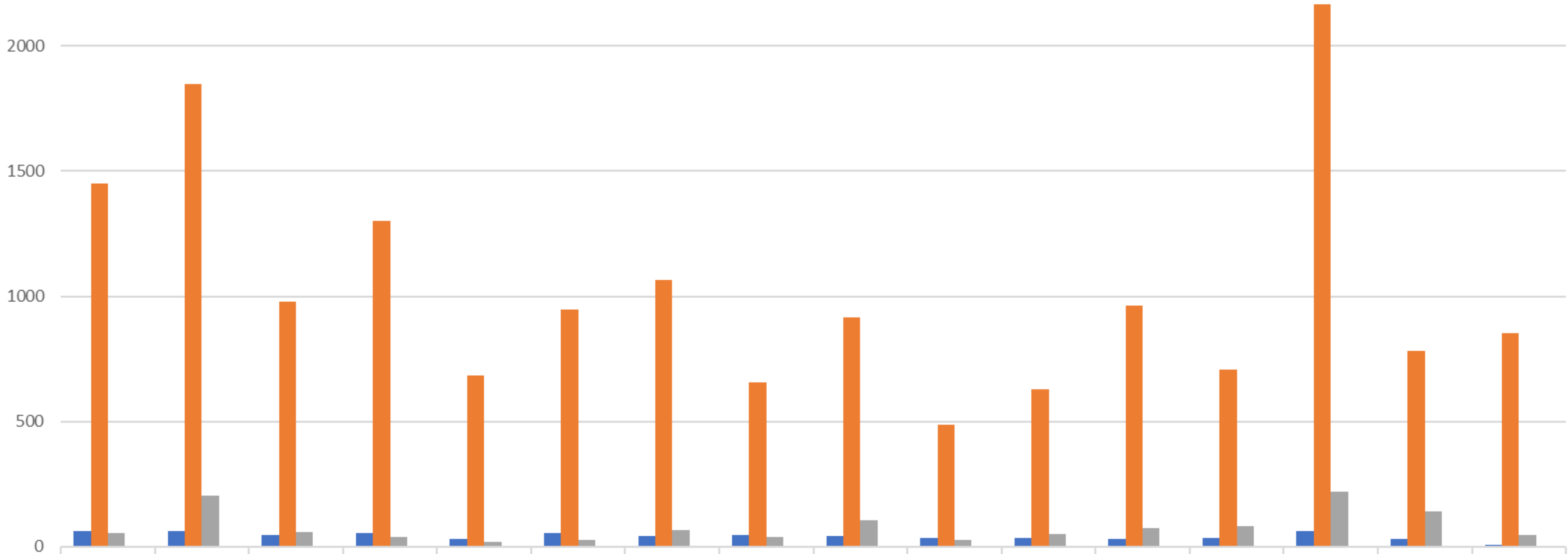
# Reality Check: Pathogens Associated with US Leafy Green Outbreaks

(CDC NORS, 2021; 2005 to 2020)




| | Norovirus | Escherichia | Cyclospora | Salmonella | | Clostridium | Staphylococcus | Shigella | Hepatitis | Bacillus | Campylobacter | Other - Chemical/ Toxin | Giardia | Listeria | Sapovirus |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Outbreaks | 340 | 76 | 9 | 66 | 112 | 16 | 15 | 8 | 2 | 13 | 7 | 3 | 1 | 4 | 1 |
| Illnesses | 8,199 | 2,442 | 1,819 | 1,489 | 1,316 | 250 | 207 | 181 | 159 | 72 | 59 | 50 | 50 | 40 | 33 |
| Deaths | 2 | 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 7 | 0 |
| Hospitalizations | 110 | 728 | 84 | 174 | 16 | 4 | 4 | 22 | 61 | 1 | 4 | 0 | 0 | 35 | 0 |

# Reality Check: US Leafy Green Outbreaks by Year
## Systemic Vulnerabilities of Supply Chain Consolidation?
(CDC NORS, 2021; 2005 to 2020)




| | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Outbreaks | 62 | 64 | 45 | 53 | 30 | 54 | 41 | 45 | 44 | 36 | 34 | 32 | 33 | 61 | 30 | 7 |
| Illnesses | 1,450 | 1,848 | 979 | 1,302 | 684 | 949 | 1,064 | 657 | 917 | 486 | 628 | 961 | 709 | 2,165 | 781 | 854 |
| Hospitalizations | 55 | 204 | 57 | 40 | 18 | 27 | 68 | 40 | 106 | 25 | 51 | 73 | 82 | 219 | 139 | 46 |
| Deaths | 0 | 5 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 4 | 1 | 0 | 4 | 5 | 0 | 0 |

# H. The Hurdle Approach–A Holistic Concept for Controlling Food Safety Risks Associated With Pathogen Contamination of Leafy Green Vegetables. A Review

(Mogren et al., 2018, *Frontiers in Microbiology 9:1-20*)

- Multi-hurdle approaches combine intrinsic (e.g., nutrients and metabolites, pH, $a_w$, antimicrobials, microbiota) and extrinsic (e.g., temperature, rainfall, irradiation, packaging) factors that can synergistically amplify pathogen suppression
- Dense and diverse microbiota of leafy greens ($8x10^3$ to $6x10^8$ cfu/g), differ by field-grown and hydroponic/laboratory media, may include
    - *Pseudomonas*, *Chryseobacterium*, *Pantoea*, *Flavobacterium*, *Ralstonia*, *Stenotrophomonas*, *Erwinia*, *Xanthomonas*, *Serratia*, *Enterobacter*, *Bacillus*, *Staphylococcus, Acinetobacter, Alkanindiges, Comamonas, Limnobacter, Pelomonas*

**A**

| Preharvest | | | Postharvest | |
|---|---|---|---|---|
| **Anabolic**<br>Building up organic material on a cellular level and as biomass<br>Basic processes: Photosynthesis, evapotranspiration, nutrient uptake and translocation | | | **Catabolic**<br>Deterioration of plant biomass<br>Basic processes: Respiration, Transpiration | |
| | Increasing plant biomass | | Static or decreasing plant biomass | |
| **Environmental factors** | **Within the canopy** | **Canopy surface** | **Factors on the leaf surface** | **Within the batch** |
| Moisture | ↑ | Variable | Moisture | ↑ |
| Temperature | ↓ | Variable | Temperature | ↑ |
| Light quality | Red and blue light ↓<br>Green light ↑ | Red and blue light ↑<br>UV abundant | Light quality | n/a |
| Atmosphere | $O_2$ rich | $O_2$ rich | Atmosphere | $CO_2$ ↑, $O_2$ ↓ |
| Available organic nutrients | Steady state* | Steady state* | Available organic nutrients | ↑ |

* intact leaf tissue

# I. Leveraging Risk Assessment for Foodborne Outbreak Investigations: The Quantitative Risk Assessment-Epidemic Curve Prediction Model

(Mokhtari et al., 2022, *Risk Analysis* 1-15)

FDA perspective

- Objective: assess possible root causes of foodborne outbreaks
- Simulate lettuce supply chain for whole and fresh cut lettuce
- Consider time-dependencies and scenarios representing post-harvest processing conditions and practices
- Comparison of simulated outbreak patterns with retrospective data from past outbreaks
- Predicted epidemic curves similar in size to past outbreaks, not strongly influenced by facility processing/sanitation conditions
- Could be used to explore potential root causes

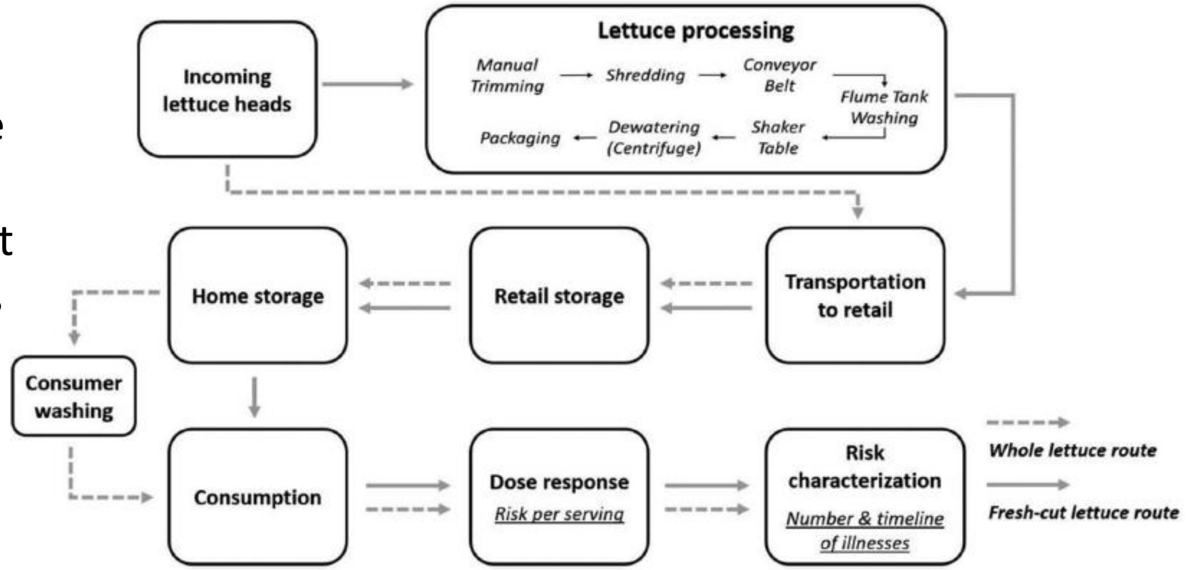



FIGURE 1 Flow diagram of the FDA leafy green quantitative risk assessment- epidemic curve model (FDA-LG QRA-EC). Solid arrows represent the supply chain for whole lettuce; Dashed arrows represent the supply chain for fresh-cut lettuce

Questions

- Unclear if multiple hurdles to suppress pathogen survival and growth were examined
- No consideration of microbiota
- No alternatives to conservative DR assumptions based on sparse data
- Uncertain conclusions may reflect correlative or causal relationships

# 4. Standardization for Evaluating and Managing Complex Systems

Risk Analysis Quality Test (RAQT, 2021)

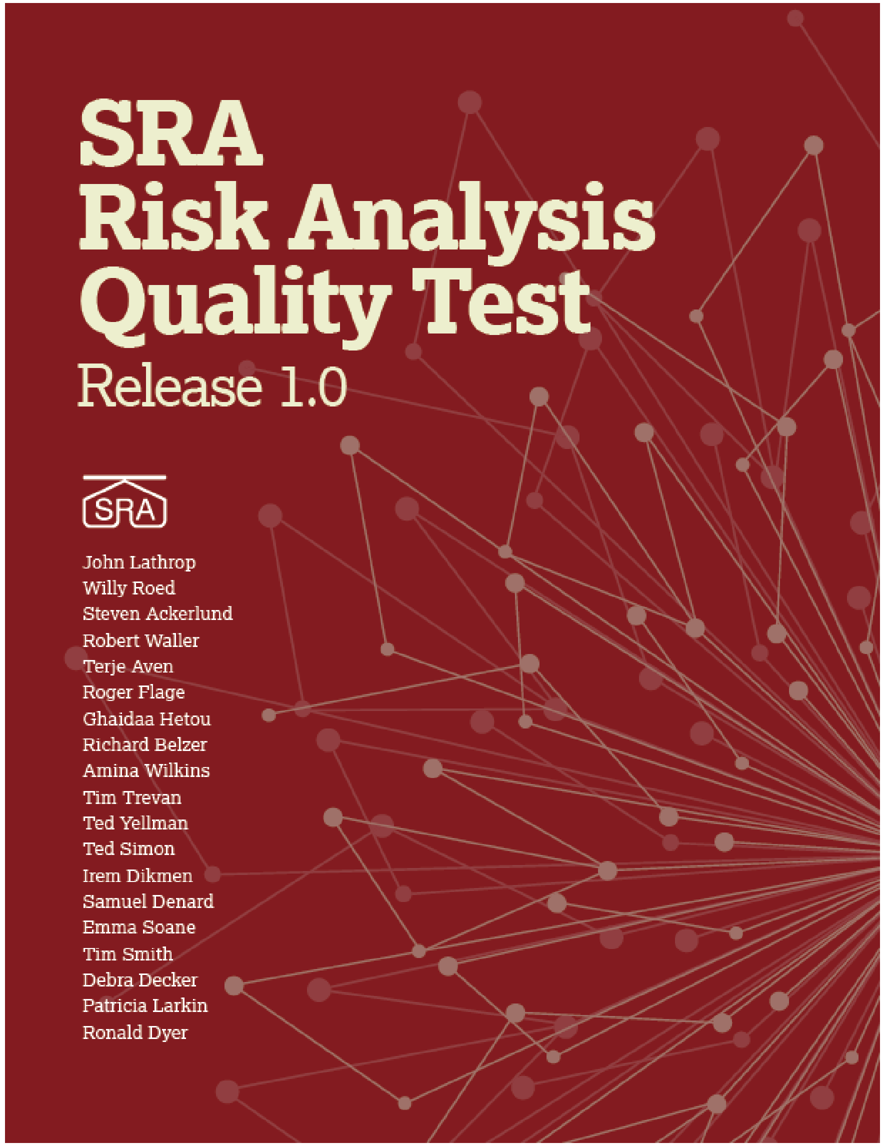
# Risk Analysis Quality Test (RAQT) of the Society for Risk Analysis

Need for developing the RAQT identified by leaders of the ARM specialty group in **2015**

Subsequent round table panels and webinars involving many diverse risk practitioners of SRA

In **2021**, RAQT v 1.0 was released, with 19 risk practitioners listed on cover: available free at https://www.sra.org/resources/risk-analysis-quality-test/

Fifteen categories, including **76 specific yes/no questions**, highly relevant to quality analysis for chemical, microbial, and physical hazards



# Fifteen Categories of the RAQT

A. Framing the Analysis and Its interface With Decision Making

B. Capturing the Risk Generating Process (RGP)

C. Communication

D. Stakeholder Involvement

E. Assumptions and Scope Boundary Issues

F. Pro-Active Creation of Alternative Courses of Action

G. Basis of Knowledge

H. Data Limitations

I. Analysis Limitations

J. Uncertainty

K. Consideration of Alternative Analysis Approaches

L. Robustness and Resilience of Action Strategies

M. Model and Analysis Validation and Documentation

N. Reporting

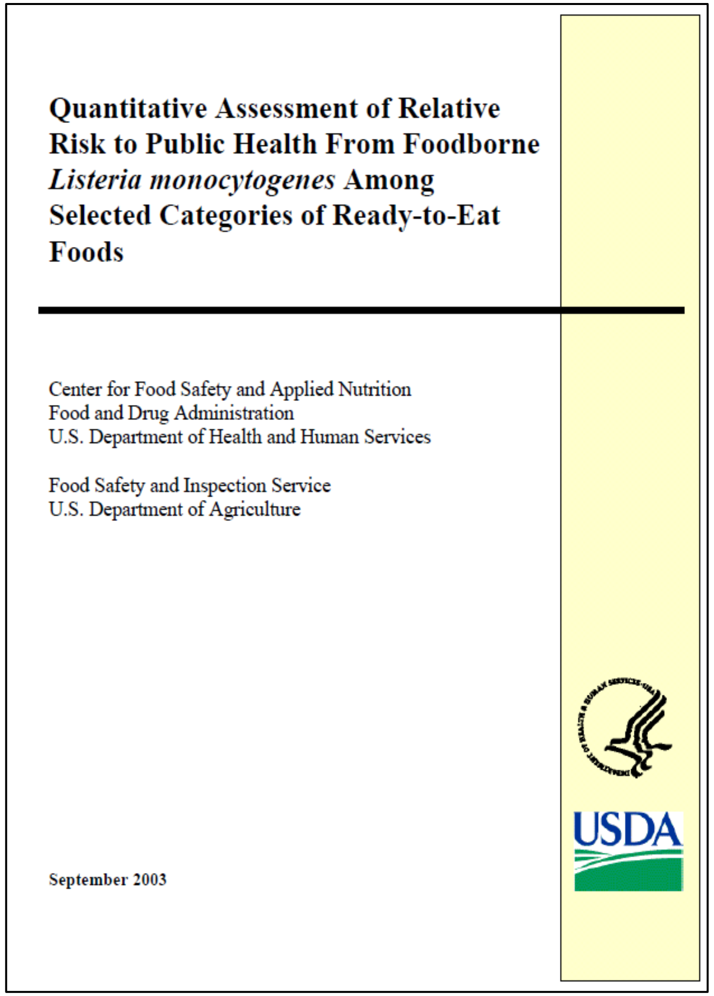
O. Budget and Schedule Adequacy

# Two QMRAs Evaluated using the RAQT

- **Joint FDA/FSIS, 2003**
  examine systematically available scientific data to estimate relative risk of **severe listeriosis** for US consumers of **23 RTE foods** (including **both raw** and **pasteurized milks**)

  (*Listeria monocytogenes* abbreviated **Lm**)

- **FSANZ, 2009**
  estimate risks and factors impacting risks along the production chain for **campylobacteriosis, listeriosis, pathogenic *E. coli*, salmonellosis** for Australian consumers of **raw milk**



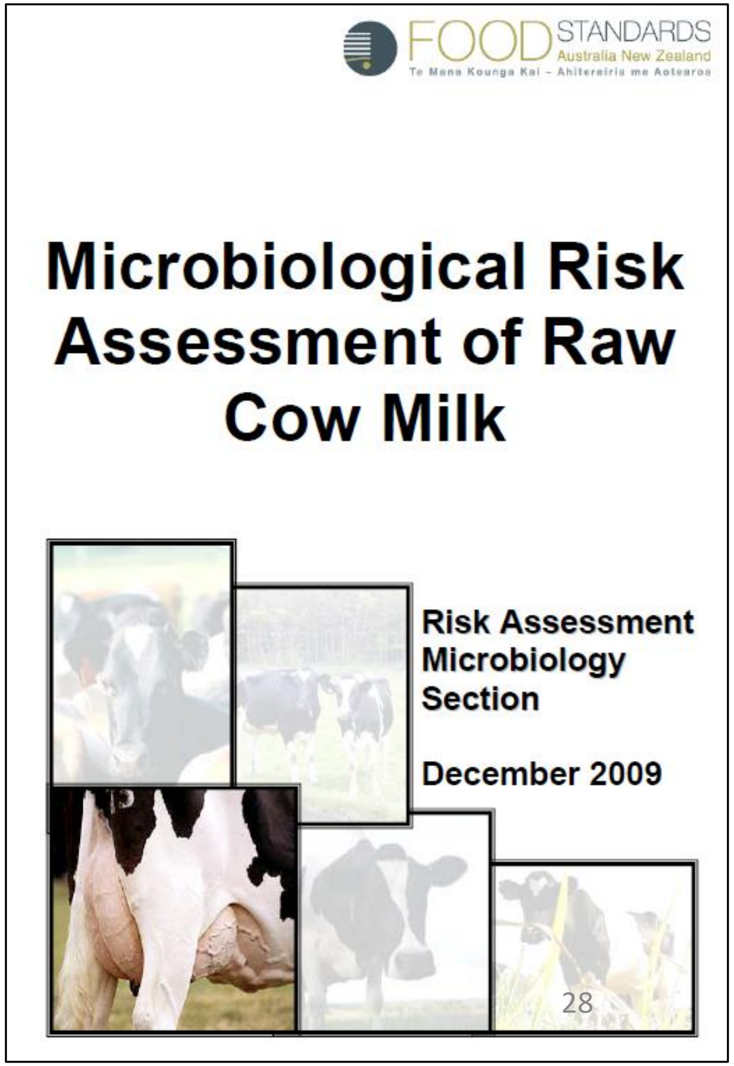
**Quantitative Assessment of Relative Risk to Public Health From Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods**

Center for Food Safety and Applied Nutrition
Food and Drug Administration
U.S. Department of Health and Human Services

Food Safety and Inspection Service
U.S. Department of Agriculture

September 2003

USDA



FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

**Microbiological Risk Assessment of Raw Cow Milk**

Risk Assessment Microbiology Section

December 2009

# Findings from Applying the RAQT to QMRAs

1. **Both QMRAs failed all 15 categories, all 76 questions in the RAQT**
   - Evidence of bias, disconnection of QMRAs with risk management decision-making, risk communication, and stakeholder involvement on alternative risk management scenarios
   - Highest priority failure of both QMRAs: **Basis of Knowledge** (scientific evidence)
     - Failure to clearly communicate to decision makers where limitations of scientific knowledge (and its basis and strength) call for risk management strategies that take those limitations into account
   - Five categories with highest priority failures for raw milk assessments:

     G. Basis of Knowledge

     A. Framing the Analysis and Its Interface With Decision Making

     J. Uncertainty: Sources, Characterization, Implications for Risk Management

     D. Stakeholder Involvement

     C. Risk Communication

2. Some **scientific data** documented, some excluded or inappropriately pooled; policy **decisions** appear based in **ideology, politics**, NOT **scientific evidence**

# RAQT Categories for Major Shortfalls to Improve Credibility of QMRAs

1. Category G. **Basis of Knowledge**
2. Category A. Framing the Analysis and Its Interface With Decision Making
3. Category J. Uncertainty: Sources, Characterization, Implications for Risk Management
4. Category D. Stakeholder Involvement
5. Category C. Risk Communication

# Findings Merit Further Analysis and Deliberation

## Evidence of Ideological or Political Bias

**FDA/FSIS (2003)**: two high risk foods with different management recommendations

- **Raw milk** "priority candidate for continued avoidance"
- **Pasteurized milk** "priority candidate for more study to confirm model predictions or identify factors not captured by current models that would reduce risk"
- No integration of risk management, little integration of risk communication
- No consideration of societal costs of interventions/recalls for foods that may not pose high risk to consumers (Farber et al., 2021)

**FSANZ (2009)**: two similar foods with same data gaps, but selection of different risk assessment methodology and management strategies

- Selection of qualitative method for **goat milk**, quantitative method (QMRA) for **cow milk**
- Assumed "little capacity for significant risk reductions" for cow milk, minimal risk for goat milk
- No integration of scenarios with risk management alternatives or with risk communication
- Concluded that "raw milk has always presented risks to public health" (for cow, not for goat); prohibition of access to cow milk, no regulation of goat milk

# ROOT CAUSES Fear and Dread of Microbes as Killer Germs; **Unquestioned Unstated Assumptions**, Speculations; Ideology and/or Politics Tipping Science

1. **The source of microbes in raw milks is feces**
   - Wu et al., 2019, 2022; Gomes et al., 2020

2. **Pasteurization is a ‘silver bullet’**

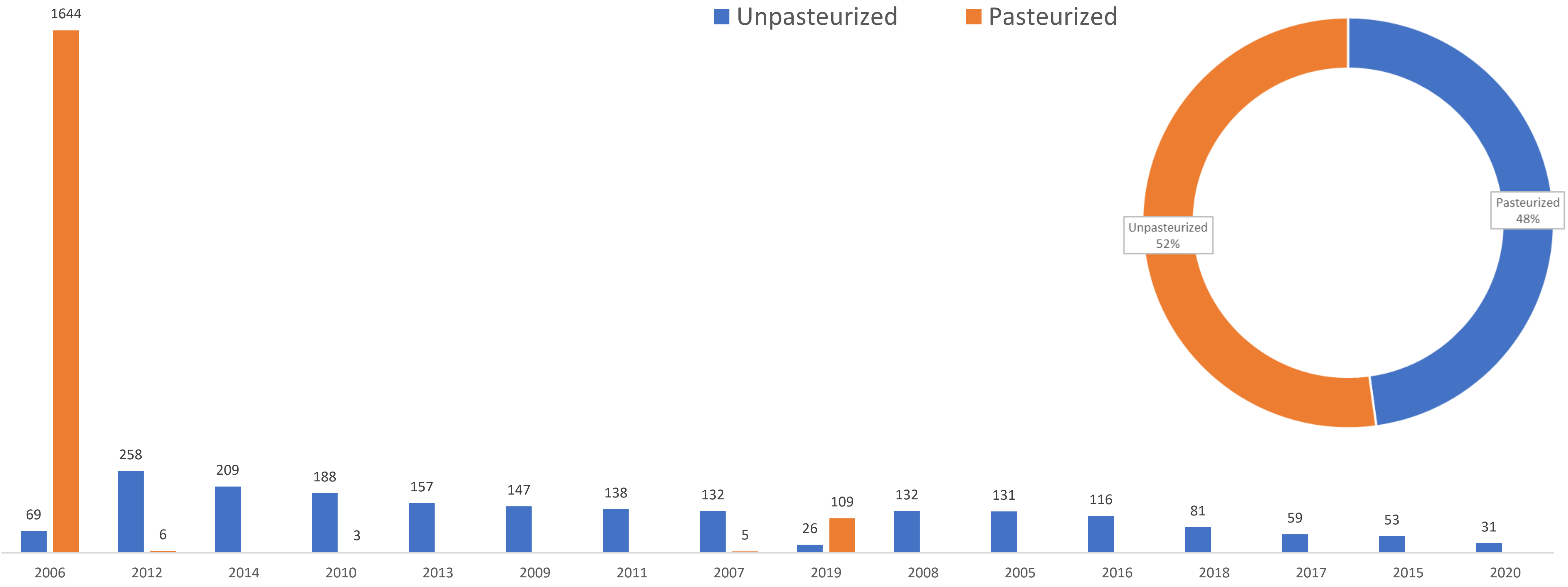
3. **Pasteurized milk is zero risk**

4. **Raw milk is ‘inherently dangerous’**

**RAQT Utility: Identify root causes (ideology, politics, and science) to enable future Evidence-Based Risk Management**

# Current Reality: US Epidemiologic Evidence Challenges Ideology, Zero-Risk Assumption for Pasteurized Milk

Illnesses associated with milk: 3,765 cases, 48% pasteurized milk (Source: CDC NORS, 2005-2020)




Deaths Rare for Milk in N America: in 16 Years, 6 US Deaths (4 pasteurized, 2 raw), 4 Canadian Deaths (pasteurized)

# Root Cause: Fear and Outrage about Raw Milk in US

Published peer-reviewed studies on next slide document urban ‘swill milk stables’ in and around large cities that contributed to high urban mortality for decades (**1840s to 1920s**)

https://www.brownstoner.com/history/walkabout-the-great-milk-wars-part-1/

- Unhealthy and dying cows in urban ‘dairies’, starved then fed hot brewery or distillery waste
- ‘Swill milk’ adulterated (added bicarbonate of soda, chalk, flour, plaster of Paris, salts, sugars, water) to mask thin bluish appearance
- ‘Swill milk’ recognized as contributor to high urban mortality, particularly infants and children
- Wealthy urban and rural families could buy or produce wholesome ‘country milk’ from healthy pasture raised cows
- **Multiple contributing factors** for high urban mortality rates at turn of the 19th century as referenced in **Dietert** et al. (2022) and project bibliography

A diseased cow, unable to stand, is pulled up to be milked. Distilleries kept a stable of such animals, fed them mash and whiskey slops. The milk made babies tipsy and often sick.

# Documentation of Sources Linked to Raw Milk Mortality

(Dietert et al., 2022)

High rates of urban vs rural mortality at the turn of 19th century attributed to multiple factors:

- Industrialization and urbanization (including dairies)
- Dangerous partnerships between distillers and urban dairies that persisted for decades
- **Urban populations** suffered **lack of**:
    - Safe water
    - Reliable systems of sewage and manure disposal
    - Reliable refrigeration during milk transport and in kitchens
    - Quality and quantity of foods for poor; undernourished, malnourished (wealthy could afford 'country milk' from pasture raised cows)
    - Healthy working conditions, adequate housing and medical care for the poor; fatigued (overcrowded, unventilated)

- Organizing Protest in the Changing City: Swill Milk and Social Activism in New York City, 1842–1864. (Egan, 2005)
- From Swill Milk to Certified Milk: Progress in Cow's Milk Quality in the 19th Century. (Obladen, 2014)
- Mortality Differentials between Rural and Urban Areas of States in the Northeastern United States 1890-1900. (Condran & Crimmins, 1980)
- Watersheds in Child Mortality: The Role of Effective Water and Sewerage Infrastructure, 1880 to 1920. (Alsan & Goldin, 2019)
- Regional and Racial Inequality in Infectious Disease Mortality in U.S. Cities, 1900-1948. (Feigenbaum et al., 2019)
- Mortality Variation in U.S. Cities in 1900: A Two-Level Explanation by Cause of Death and Underlying Factors. (Crimmins & Condran, 1983)

# Current Reality: Milk Microbiota Outcompetes Pathogens

Consider synergistic multi-hurdle options including microbial competition
of pathogens with dense diverse natural microbiota of milks

### Human

Ralstonia
Roseburia
Clostridium
Corynebacterium
Faecalibacterium
Lactobacillus
Bifidobacterium
Propionibacterium
Pseudomonas
Staphylococcus
Streptococcus
Bacteroides
Acinetobacter
Veillonella
Lachnospiraceae
Ruminococcaceae
Enterococcus
Prevotella
Weisella
Leuconostoc
Lactococcus
Citrobacter
Serratia

### Cow

Microbacterium
Pediococcus
Fusobacterium
Propionibacterium
Acinetobacter
Bifidobacterium
Pseudomonas
Staphylococcus
Streptococcus
Lachnospiraceae
Corynebacterium
Bacteroides
Enterococcus
Ruminococcaceae
Aerococcus
Jeotgalicoccus
Psychrobacter
Enterobacter

### Water buffalo

Micrococcus
5-7N15
Solibacillus
Propionibacterium
Pseudomonas
Staphylococcus
Aerococcus
Clostridium
Facklamia
Trichococcus
Turicibacter
Acinetobacter
Psychrobacter

### Goat

Micrococcus
Rhodococcus
Arthrobacter
Stenotrophomonas
Pseudomonas
Staphylococcus
Streptococcus
Phyllobacterium
Rhizobium
Agrobacterium
Bacillus

### Sheep

Enterococcus
Bifidobacterium
Lactobacillus
Pseudomonas
Staphylococcus
Streptococcus
Corynebacterium
Bacillus
Methylobacterium
Escherichia

Oikonomou et al., 2020, Figure 2, https://www.frontiersin.org/articles/10.3389/fmicb.2020.00060/full

# Intention for Managing Higher Risk Foods

- FDA/FSIS framed analysis with the expectation that foods ranked higher might be targets for additional risk management measures
  - Identified **Deli Meats** (very high risk) and conducted subsequent analysis (**Gallagher** et al., 2003, 2016; Mamber et al., 2020); see background slides
  - identified **Pasteurized Milk** (high risk) as a "priority candidate for advanced epidemiologic and scientific investigations to **either confirm** predictions of the risk assessment or **identify the factors not captured** by the [2003] models that would reduce predicted relative risk"
  - identified **Raw Milk** (also high risk) as a "priority candidate for **continued avoidance**"
    - **Schmidt** et al. (2020) paper on structural nonidentifiability raises issues relevant to this point; insufficient information about important parameters can lead to misleading models and unreliable results
    - Factor not captured by the 2003 model: effect of **Lm** suppression by competing natural microbiota of raw milks; questionable pooling for growth studies; overestimate for **Lm** prevalence (4%) reflecting pre-pasteurization milk, not raw milk produced for direct human consumption (currently <0.01%, **Dietert** et al., 2022)

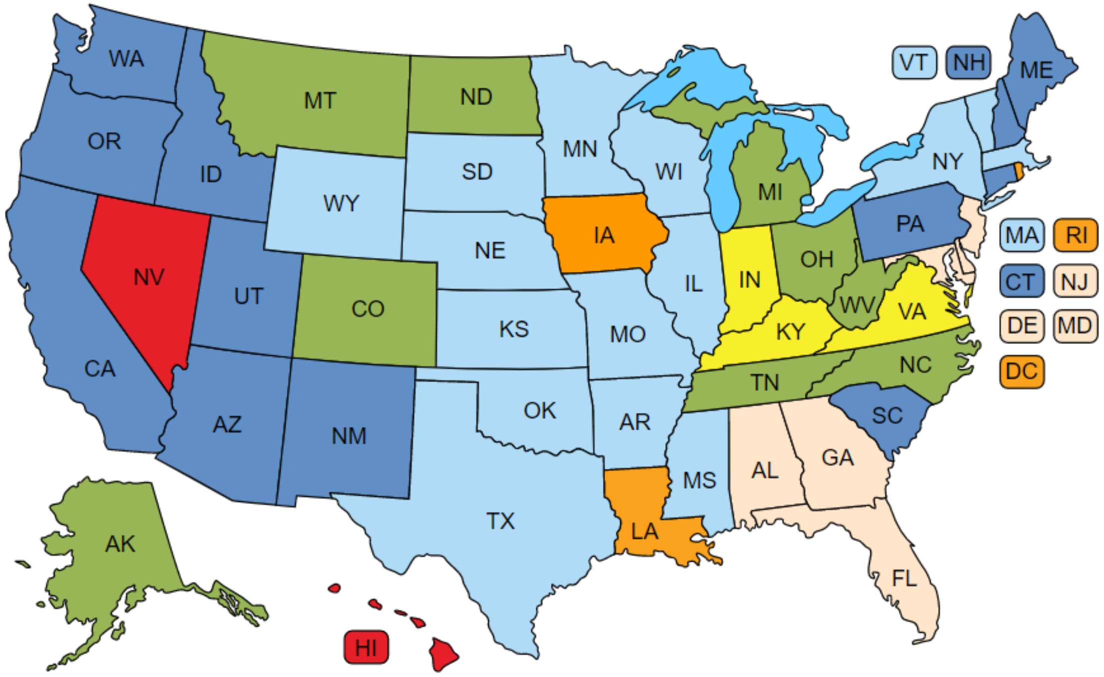
# Risk Management Basis Ideology? Science?

- FSANZ based 2009 analysis on unvalidated assumptions due to lack of data for raw milk microbiology and consumption in Australia and New Zealand

- FSANZ began its conclusion section with this statement:
  - "Raw cow milk has always presented risks to public health [and always will?] because of the potential presence of pathogenic bacteria."
    (FSANZ, 2009, page 42)

- FSANZ Chief Executive Officer Mark Booth memo (2021)
  - No studies were conducted to fill data gaps identified in 2009 QMRA
  - Applying data would not change their assessment

# Real Milk Interactive Map on Legal Access to Raw Milks




**BLUE** Retail sales legal

**CYAN** On-farm sales legal — This category includes sales through delivery, at farmers market, and at any other venues where direct raw milk producer-to-consumer transactions are allowed.

**GREEN** Herdshares legal — by statute, regulation, court decision, or written policy

**YELLOW** No law on herdshares — The state is aware herdshare operations exist but has taken no action to stop them.

**PEACH/MELON** Sales of raw pet milk legal—farmers are selling raw pet dairy products

**ORANGE** Sales of raw pet milk legal—distributed only by national raw pet dairy manufacturers but there are no farmers selling raw pet milk

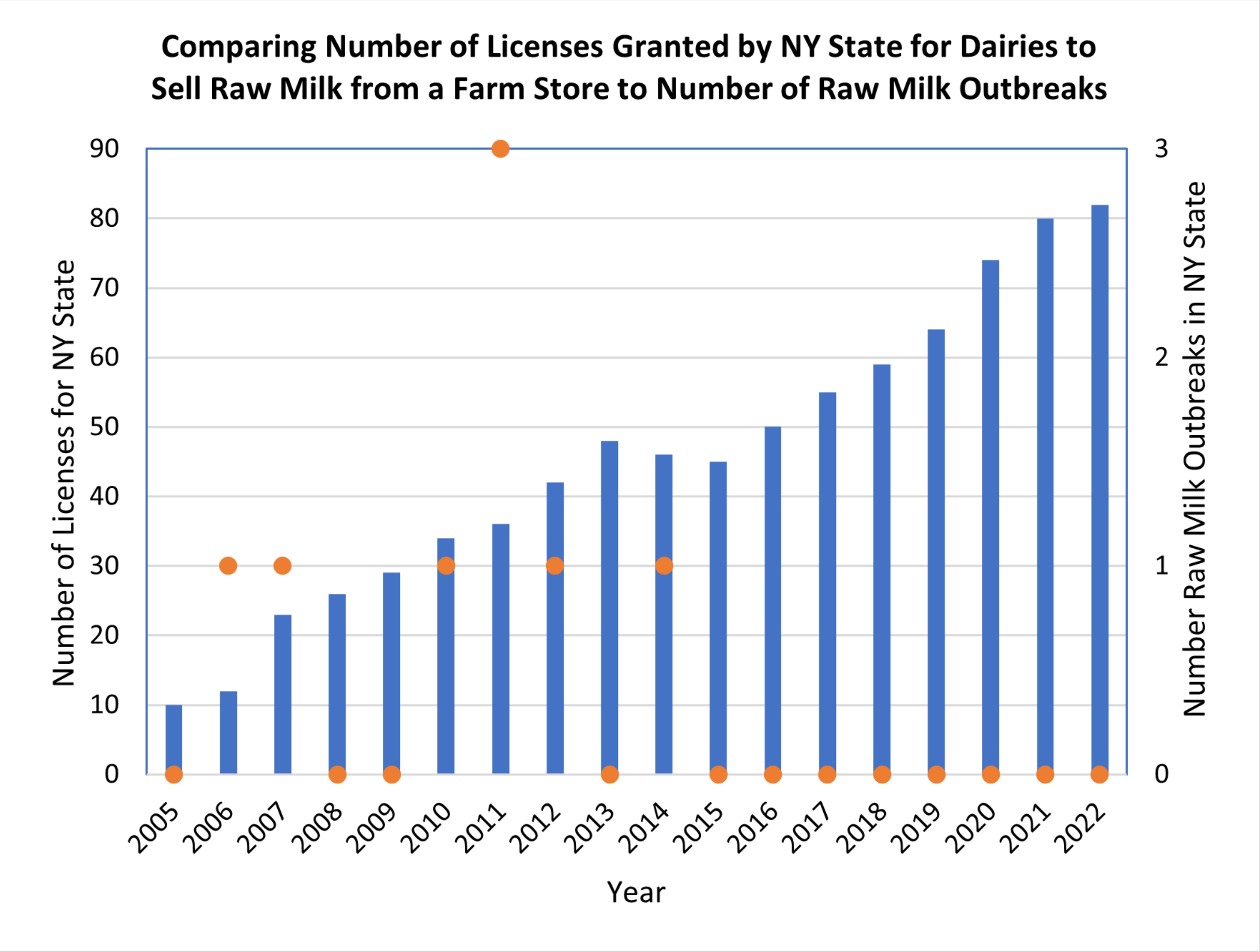
**RED** All sales and distribution of raw milk illegal — Nevada is the only state in this category; it allows the sale of raw pet milk but only if a toxic denaturant is added

https://www.realmilk.com/real-milk-legal-map/, last updated 11 Nov 2022

# Reality for 2022: NY State Licensed 82 Raw Milk Dairies

- NY State data on numbers of licenses for **on-farm** raw milk sales (obtained by FOIA)

- US CDC NORS outbreaks (2005-2020)
  - ➢ Eight NY state outbreaks in 16 years
    - 58 **campylobacteriosis** illnesses (4 hospitalizations, 0 deaths)
  - ➢ **No raw milk outbreaks** reported in NY state since **2014** despite increasing numbers of licenses for farms legally selling raw milk (data obtained by FOIA)
  - ➢ **Pathogens NOT associated with NY state outbreaks** (since at least 1998):
    - *Salmonella* spp.
    - Pathogenic *E. coli* (EHEC/STEC/VTEC)
    - *Listeria monocytogenes*



# Reality for California Retail Raw Milk Producer

## Production, Test & Hold Monitoring, Epidemiology

- **Retail raw milk** production = **1.4 Million Gallons** (2018 – 2020)

- Equivalent to **20,480,000 servings** of 250 mL

- Test-and-Hold Monitoring for period ➡

| **Country** (Reference) | **Dates (State)** | ***Campylobacter*** | ***E. coli* O157:H7 or EHECs** | ***L. monocytogenes*** | ***Salmonella*** |
|---|---|---|---|---|---|
| **US** (Stephenson & Coleman, 2021) | 2018-2020 (CA) | 15 positives, 2 presumptives diverted of 123 (13.8%) | **0** diverted of 898 | **0** diverted of 109 | **0** diverted of 109 |

- **No raw milk outbreaks**
  - *Campylobacter* spp.
  - *Salmonella* spp.
  - *E. coli* O157:H7 (EHEC/STEC/VTEC)
  - *Listeria monocytogenes*

- Risk of illness **<1 in over 20 million servings** for CA retail raw milk consumers

**'inherently dangerous'?**

# Reality for Ohio Outbreaks: Legal HerdShare Sales

| CDCID | Year | Confirmed Cases | Number Hospitalized | Number Deaths |
|---|---|---|---|---|
| 256867 | 2006 | 3 | 1 | 0 |
| 12180 | 2012 | 2 | 0 | 0 |
| 267589 | 2015 | 2 | 2 | 0 |
| 270695 | 2016 | 11 | 2 | 0 |
| 290948 | 2019 | 7 | 1 | 0 |

- Five confirmed raw milk outbreaks in Ohio, with total of 25 illnesses, 6 hospitalizations, no deaths all associated with campylobacteriosis in 16-year period (2005-2020; CDC, 2021)

- **No confirmed raw milk outbreaks**
  - *Salmonella* spp.
  - *E. coli* O157:H7 (EHEC/STEC/VTEC)
  - *Listeria monocytogenes*
- *Return of the Milk Man in Ohio* (2018; buying club, herdshare) (https://www.realmilk.com/return-milkman-ohio/)

# Reality Check: Extremely Low Percentage of Pathogen Positives for Raw Milk Produced for Direct Human Consumption in Recent Decade of Monitoring Programs in US and around the World

| **Raw Milk Monitoring: Canada, Finland, Germany, Poland, UK, US** | ***Campylobacter*** | ***E. coli* O157:H7 or EHECs** | ***L. monocytogenes*** | ***Salmonella*** |
|---|---|---|---|---|
| **OVERALL PERCENTAGE POSITIVE** | 93/9,740 (0.01%) | 26/10,934 (<0.01%) | 40/9,118 (<0.01%) | 14/7,976 (<0.01%) |

Extracted from detailed table in **Dietert** et al. (2022)

No recent evidence from monitoring or epidemiology that raw milk is 'inherently dangerous'

# Reality Check: Ideology, Politics, and Science Driving QMRAs and Peer Review?

**Sebastianski** et al. (2022). Disease outbreaks linked to pasteurized and unpasteurized dairy products in Canada and the United States: a systematic review. Canadian Journal of Public Health, 1-10.

## Authors' conclusion not supported by data and analysis

- **Results**: "*Listeria monocytogenes* was **more likely** to be the causative agent in **pasteurized** outbreaks (*Listeria*: n=10/12, 83% versus *non-Listeria*: n=2/12, 17%; p<0.001) and the **proportions of hospitalizations and deaths** were **higher** in **pasteurized** than in unpasteurized outbreaks (pasteurized: n=134/284, 47% vs. unpasteurized: n=124/530, 23%, p<0.01; pasteurized: 17/284, 6% vs. unpasteurized: 5/530, 0.9%, p<0.01) respectively."
- **Conclusion:** "**Public warnings about the risk of unpasteurized dairy consumption need to continue** and pregnant women and immunocompromised hosts need to be made aware of foods at high risk of contamination with *Listeria*."

## Ideology or Belief that Pasteurization is a 'Silver Bullet' ensuring Safety?

Decision makers (and authors of peer-reviewed papers, journal reviewers and editors) are not immune to ideological bias, despite statistical evidence of enhanced likelihood and more severe risk for pasteurized dairy.

# Failure to Communicate Limitations of Scientific Knowledge that Merit Incorporation into Risk Management Strategies

- The strength of the Basis of Knowledge reported by FDA/FSIS (2003) was poor and misleading for some foods/food groups. Pooling disparate, significantly different growth rates for two separate foods (raw and pasteurized milk) was not justified scientifically.
  - FDA/FSIS cited Northolt et al. (1988) report documenting *Lm* grew **faster** in **pasteurized** milk (0.407 cfu/g∗day) than **raw milk** (0.085 cfu/g∗day) at refrigeration temperatures; **applied one 'average' growth rate** (0.257 cfu/g∗day)
- Multiple studies question application of intentionally conservative assumptions for dose-response relationships, especially for a ubiquitous pathogen rarely causing severe illness likely due to high thresholds for innate resistance of healthy people.
  - **Chen** et al., **2003**; **Buchanan** et al., **2017**; **Rahman** et al., **2016**, **2018**, **2020**
- Imposing 'zero tolerance' for *Lm* in RTE foods (declared adulterated based solely on pathogen presence) merits wider deliberation (**Farber** et al., **2021**).

**Monitoring raw milk with a naturally dense and diverse microbiota that suppresses *Lm* and imposing 'zero tolerance' for detection of any level of *Lm* appears to reflect ideology, not science.**

# Reality Across US States: Few Raw Milk Outbreaks over 16 Years

31 States Reported 0, 1, or 2 Raw Milk Outbreaks from 2005 - 2020

| 1 | 2 | 3 - 5 | 6 – 13 | >24 |
|---|---|---|---|---|
| Georgia | **Arizona** | Alaska (3) | Michigan (6) | **Pennsylvania (25)** |
| Indiana | **Connecticut** | **Iowa (3)** | **Idaho (8)** | |
| Kentucky | Florida | Vermont (3) | **California (8)** | |
| Montana | Kansas | Illinois (4) | New York (8) | |
| **New Mexico** | **Maine** | Massachusetts (4) | **Washington (9)** | |
| North Carolina | Missouri | Multistate (4) | Colorado (9) | |
| **Oregon** | **New Hampshire** | **South Carolina (4)** | Minnesota (10) | |
| | North Dakota | Wisconsin (4) | Ohio (13) | |
| | Oklahoma | Tennessee (5) | **Utah (19)** | |
| | Virginia | Texas (5) | | |
| | Wyoming | | | |

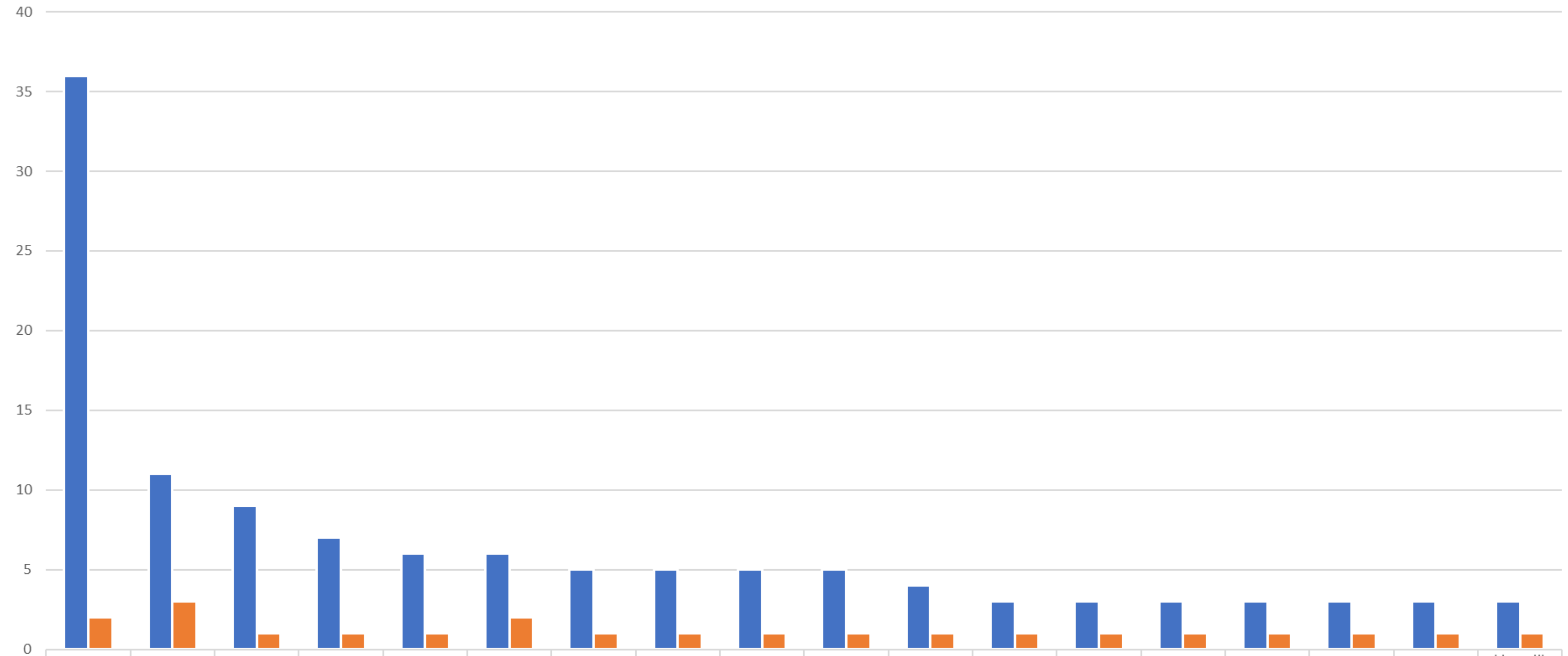
Text Color Code for Legal Status: **navy retail**; blue farm store; green herdshare legal; yellow no herdshare prohibition; mustard pet milk legal

# Reality Check: Foods Associated with Outbreaks Reporting 1 or 2 Deaths

(Source: CDC NORS, 2005-2020)

| | | | | |
|---|---|---|---|---|
| **ackawi cheese, pasteurized\|chives cheese, pasteurized** | cucumber | **ice cream, commercial (pasteurized)** | oysters, raw | soup, jambalaya |
| alfalfa sprouts\|alfalfa sprout seeds | **dairy products (unspecified)** | Italian-style deli meats | oysters\|oysters, raw | steak, sirloin |
| **artisinal soft cheese, unpasteurized** | deli products | latin style soft cheese | papaya | stone fruit |
| avocado, unspecified | eggs | leafy greens | peaches | strawberries |
| beef | eggs, hard boiled | lettuce | peppers, jalapeno\|tomato, unspecified\|peppers, serrano | taco combo meal |
| beef\|latin style soft cheese | eggs, over-easy | lettuce based salads, unspecified | pork | tahini |
| beets | Enoki Mushroom | meatballs\|roast beef | pork rib tips | tomato |
| blue-veined cheese, unpasteurized | fermented fish heads | melon | potato | turkey |
| cantaloupe | fruit salad | melon, unspecified | pre-packaged leafy greens | turkey, baked |
| cantaloupe\|ground beef, unspecified | gravy | **Mexican cheese (queso fresco and/or other)** | pre-packaged salad | turkey, unspecified |
| carrot juice, pasteurized | ground beef | **Mexican style cheese, pasteurized** | pureed food diet | venison |
| carrots\|oil\|onion\|oregano\|tomato\|pepper, chili\|vinegar | ground beef, other | **milk (unpasteurized)** | **queso fresco, pasteurized** | vine-stalk e.g., tomato |
| **Cheese (unspecified)** | ground beef\|lettuce\|sprouts | **milk\|milk (pasteurized)** | rice | watermelon |
| **cheese, pasteurized** | ground turkey, unspecified | mung bean sprouts | salmon, unspecified | whale |
| chicken salad | herbal tea | nachos and cheese | sausage, pork | |
| chicken\|steak | home-canned vegetable, unspecified | **other cheese, pasteurized** | smoked fish | |
| country style deli ham | hummus | oysters | **soft cheese** | |

# Reality Check: Raw Milk not among Foods Associated with >2 Deaths
## (Source: CDC NORS, 2005-2020)

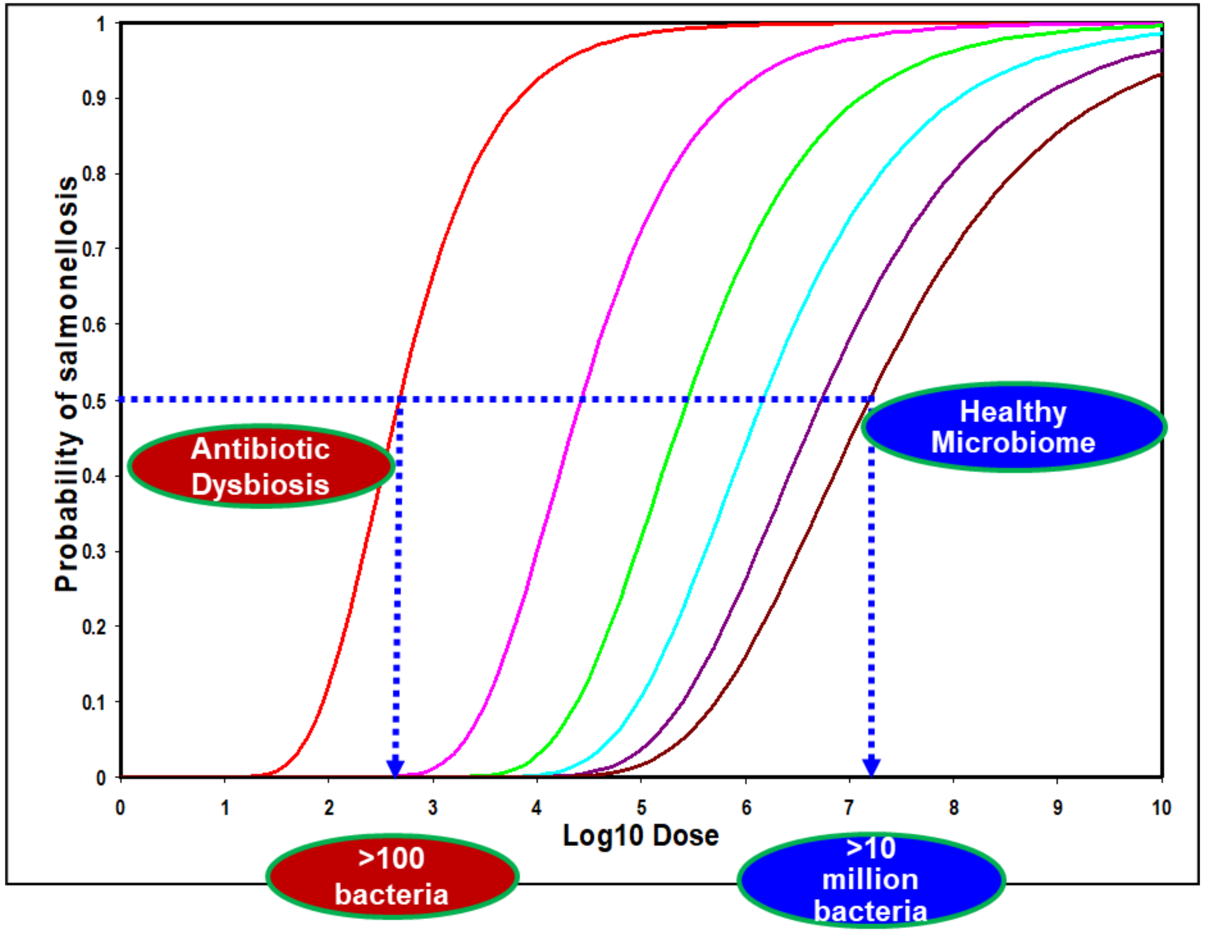



| | cantaloupe | unknown | Peanut Butter\| Peanut Paste | apple | cucumber | prepackaged leafy greens | spinach | romaine lettuce | celery, unspecified | ricotta salata cheese | Enoki Mushroom | pot pie | hummus | tuna salad | turkey | vegetables, unspecified | ice cream, commercial | skim milk, pasteurized\| other milk, pasteurized |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Number of Deaths | 36 | 11 | 9 | 7 | 6 | 6 | 5 | 5 | 5 | 5 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Outbreaks | 2 | 3 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

# Dose-Response Model Uncertainty

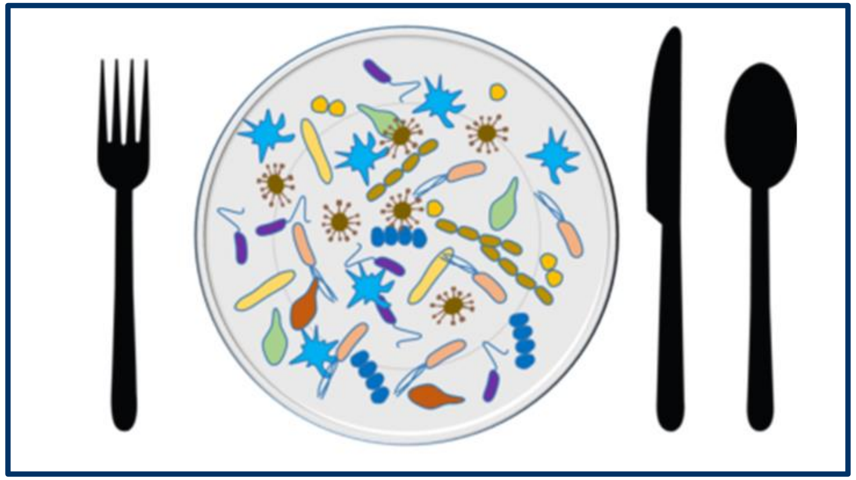
Both QMRAs selected and applied intentionally conservative (biased) assumptions or simplistic models that overestimated risk and underestimated uncertainties, particularly for dose-response relationships that are complex, dynamic, and multi-factorial

- **Marks** et al. (1998) and **Coleman** et al. (2021): conservative non-threshold, low-dose linear models ignore innate and adaptive immunity, microbial ecology of healthy GI
- **Powell** et al. (2000) *Dose-Response Envelope for E. coli O157:H7*
- **FDA/FSIS** (2003) 'anchored' conservative **Lm** DR model to epidemiologic data to lower risks by applying linear scaling factors as high as 13-orders of magnitude.
- **Chen** et al. (2003) *Listeria monocytogenes*: *Low Levels = Low Risk*
- **FDA** (2008) reported that the model results adjusted for epidemiologic evidence did not attribute any cases of listeriosis to food servings until **Lm** growth exceeded **100,000 counts** (colony forming units) per serving
- **Former FDA Scientific Advisor Buchanan** et al. (2017) noted that thresholds >10,000 Lm cells drove simulated cases, also documented by mechanistic modeling work of **Rahman** et al. (2018)
- **Oscar** (2021) *Salmonella Prevalence Alone Is Not a Good Indicator of Poultry Food Safety*

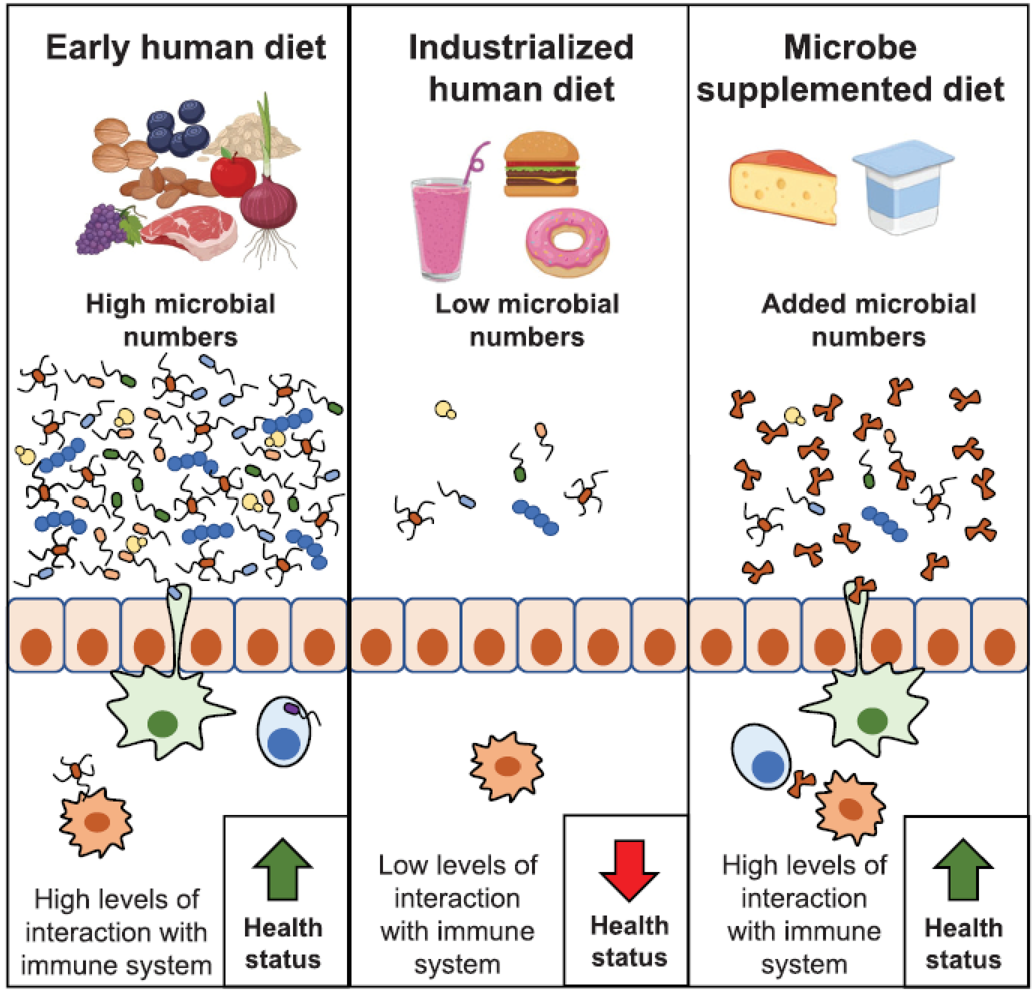



**Coleman** et al., 2018. Figure 2

# Consider *Recommended Daily Allowances for Microbes* (*$RDA_M$*) as for Vitamins



(Hill, 2018)




**Whole Foods Contribute More than Nutrients for Human Cells**

(Marco et al., 2020)

# Acknowledgements

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# Backup Slides Appended

COLEMAN SCIENTIFIC CONSULTING

**Emails:** colemanmellen@gmail.com; peg@colemanscientific.org

# Backup Slides

applied microbiology

an Open Access Journal by MDPI

Enhancing Human Superorganism Ecosystem Resilience by Holistically 'Managing Our Microbes'

Margaret E. Coleman; Rodney R. Dietert; D. Warner North; Michele M. Stephenson

*Appl. Microbiol.* **2021**, Volume 1, Issue 3, 471-497

applied microbiology

an Open Access Journal by MDPI

Examining Evidence of Benefits and Risks for Pasteurizing Donor Breastmilk

Margaret E. Coleman; D. Warner North; Rodney R. Dietert; Michele M. Stephenson

*Appl. Microbiol.* **2021**, Volume 1, Issue 3, 408-425

applied microbiology

an Open Access Journal by MDPI

Nourishing the Human Holobiont to Reduce the Risk of Non-Communicable Diseases: A Cow's Milk Evidence Map Example

Rodney R. Dietert; Margaret E. Coleman; D. Warner North; Michele M. Stephenson

*Appl. Microbiol.* **2022**, Volume 2, Issue 1, 25-52

# Summary Table 1, Predicted Median Listeriosis Cases per Serving and per Annum
(FDA/FSIS, 2003)

- Agencies announced intent to conduct a listeriosis risk assessment in 1999
- Tremendous level of effort compiling, generating, and incorporating data for 23 foods/food groups (outbreak-associated)
- Multiple public meetings, expert consultations, and 6-month public comment period for 2001 drafts: assessment, risk management action plan (backup slide)
- Documentation of evidence and parameters used to estimate risks
- Simulated servings containing **>10,000 Lm** drove relative risk estimates

| Relative Risk Ranking | Predicted Median Cases of Listeriosis for 23 Food Categories | | | | | |
|---|---|---|---|---|---|---|
| | Per Serving Basis[a] | | | Per Annum Basis[b] | | |
| | | Food | Cases | | Food | Cases |
| 1 | High Risk | Deli Meats | $7.7 \times 10^{-8}$ | Very High | Deli Meats | 1598.7 |
| 2 | | Frankfurters, not reheated | $6.5 \times 10^{-8}$ | High Risk | Pasteurized Fluid Milk | 90.8 |
| 3 | | Pâté and Meat Spreads | $3.2 \times 10^{-8}$ | | High Fat and Other Dairy Products | 56.4 |
| 4 | | Unpasteurized Fluid Milk | $7.1 \times 10^{-9}$ | | Frankfurters, not reheated | 30.5 |
| 5 | | Smoked Seafood | $6.2 \times 10^{-9}$ | Moderate Risk | Soft Unripened Cheese | 7.7 |
| 6 | | Cooked Ready-to-Eat Crustaceans | $5.1 \times 10^{-9}$ | | Pâté and Meat Spreads | 3.8 |
| 7 | Moderate Risk | High Fat and Other Dairy Products | $2.7 \times 10^{-9}$ | | Unpasteurized Fluid Milk | 3.1 |
| 8 | | Soft Unripened Cheese | $1.8 \times 10^{-9}$ | | Cooked Ready-to-Eat Crustaceans | 2.8 |
| 9 | | Pasteurized Fluid Milk | $1.0 \times 10^{-9}$ | | Smoked Seafood | 1.3 |
| 10 | Low Risk | Fresh Soft Cheese | $1.7 \times 10^{-10}$ | Low Risk | Fruits | 0.9 |
| 11 | | Frankfurters, reheated | $6.3 \times 10^{-11}$ | | Frankfurters, reheated | 0.4 |
| 12 | | Preserved Fish | $2.3 \times 10^{-11}$ | | Vegetables | 0.2 |
| 13 | | Raw Seafood | $2.0 \times 10^{-11}$ | | Dry/Semi-dry Fermented Sausages | <0.1 |
| 14 | | Fruits | $1.9 \times 10^{-11}$ | | Fresh Soft Cheese | <0.1 |
| 15 | | Dry/Semi-dry Fermented Sausages | $1.7 \times 10^{-11}$ | | Semi-soft Cheese | <0.1 |
| 16 | | Semi-soft Cheese | $6.5 \times 10^{-12}$ | | Soft Ripened Cheese | <0.1 |
| 17 | | Soft Ripened Cheese | $5.1 \times 10^{-12}$ | | Deli-type Salads | <0.1 |
| 18 | | Vegetables | $2.8 \times 10^{-12}$ | | Raw Seafood | <0.1 |
| 19 | | Deli-type Salads | $5.6 \times 10^{-13}$ | | Preserved Fish | <0.1 |
| 20 | | Ice Cream and Other Frozen Dairy Products | $4.9 \times 10^{-14}$ | | Ice Cream and Other Frozen Dairy Products | <0.1 |
| 21 | | Processed Cheese | $4.2 \times 10^{-14}$ | | Processed Cheese | <0.1 |
| 22 | | Cultured Milk Products | $3.2 \times 10^{-14}$ | | Cultured Milk Products | <0.1 |
| 23 | | Hard Cheese | $4.5 \times 10^{-15}$ | | Hard Cheese | <0.1 |

# Reality Check: FDA/FSIS (2003) Predicted Relative Risks versus Recent Listeriosis Deaths

- Individual Foods (9 Dairy Foods)
  (6 cheese groupings by moisture content, +correlated w/growth potential)
  **Relative Risk per Serving**
  1. **Deli meats**
  2. **Pasteurized milk**
  5. Soft unripened cheese
  7. **Raw milk**
  10. **Fruits**
  12. **Vegetables**
  14. Fresh soft cheese
  15. Semi-soft cheese
  16. Soft ripened cheese
  20. **Ice cream** and other frozen dairy products
  21. Processed cheese
  23. Hard cheese

- Dairy Food Groups (2)
  **Relative Risk per Serving**
  3. High fat and other dairy products
     (butter, cream, half and half, milk shakes, cocoa, chocolate syrup, eggnog, margarine, veg. oil spread)
  22. Cultured milk products (yogurt, buttermilk, sour cream)

5 celery, 33 cantaloupe,
1 caramel apples, 1 **raw** milk,
2 ice cream from **pasteurized** milk,
4 **pasteurized** chocolate milk,
2 mung bean sprouts,
1 deli products

# FDA/FSIS Risk Management Action Plan (2001)

1. Enhance **consumer** and **health care provider** information and **education** efforts;

2. Develop and revise **guidance** for **processors, retailers, and food service/ institutional establishments** that manufacture or prepare ready-to-eat foods;

3. Develop and deliver **training/ technical assistance** to the regulated **industry** and **food safety regulatory employees**;

4. Review and redirect **enforcement** and **regulatory strategies** including product sampling;

5. Propose new **regulations** and **revisions** to existing regulations as needed;

6. Enhance **disease surveillance** and outbreak response;

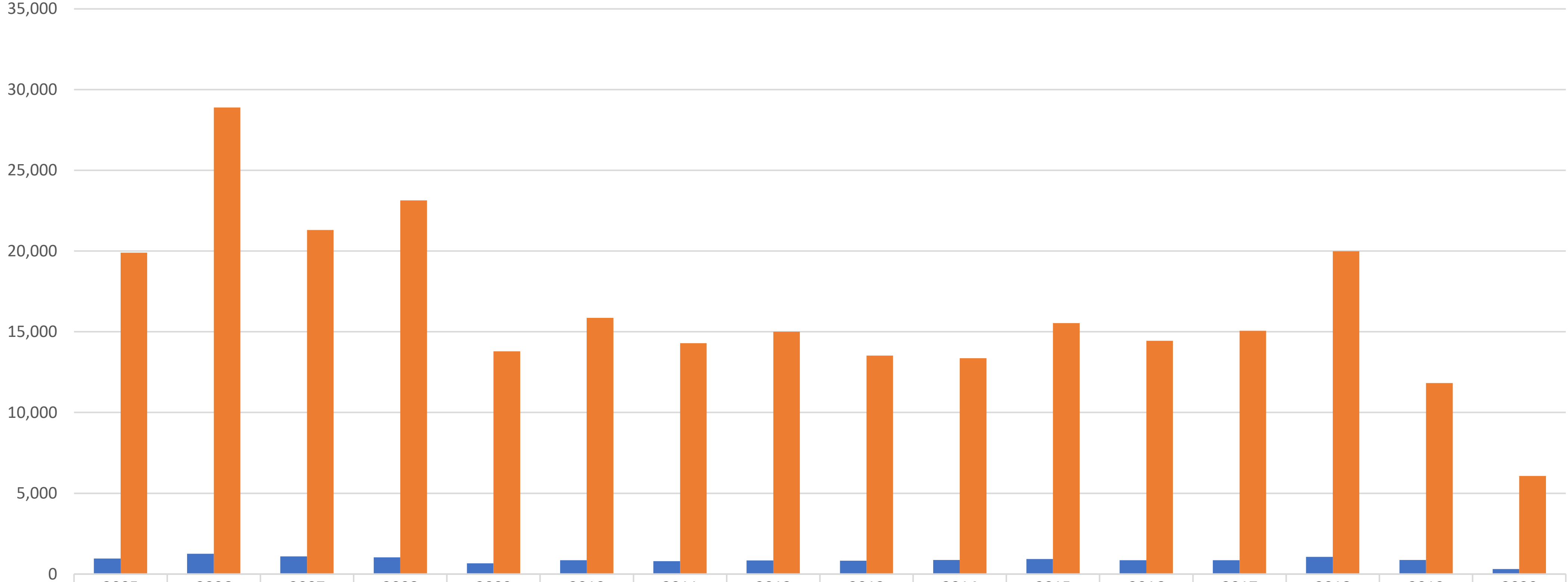
7. Initiate projects with **retail** operations (e.g. delicatessens, salad bars) to pilot new Lm **control measures** including **employee practices**; and

8. Coordinate **research** activities to **refine** the risk **assessment**, enhance preventive **controls**, and support **regulatory, enforcement, and educational activities**.

# Codex Alimentarius Commission (CAC, 1999)
## General Principles of Microbiological Risk Assessment

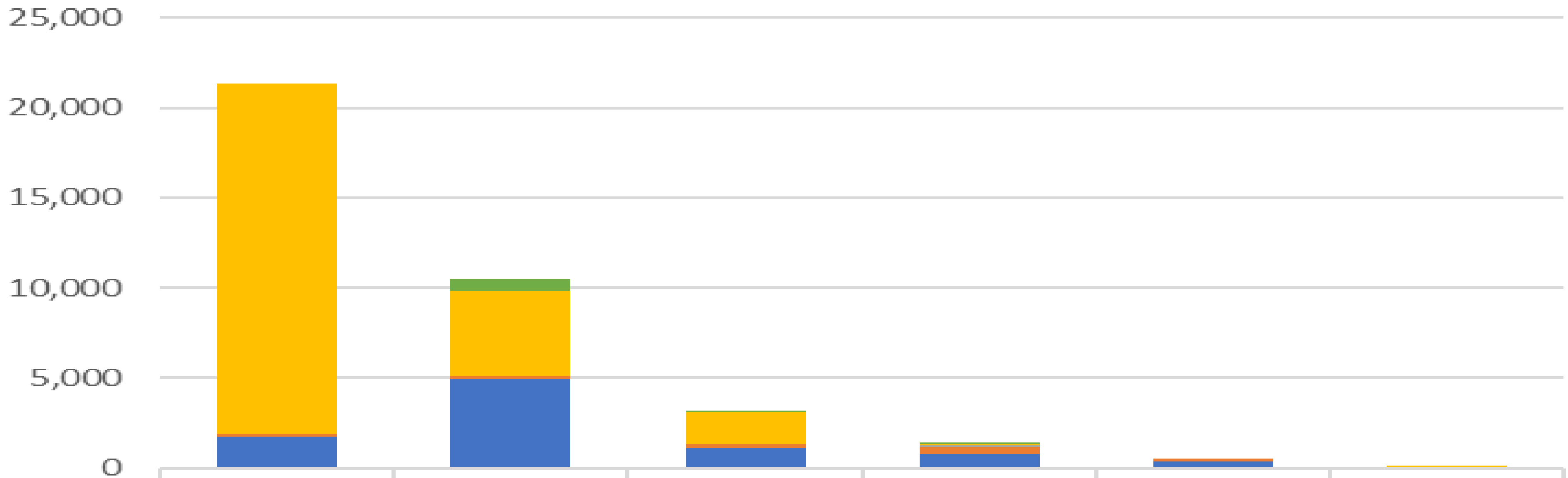
1. Microbiological Risk Assessment should be soundly based upon science.
2. There should be a functional separation between Risk Assessment and Risk Management.
3. Microbiological Risk Assessment should be conducted according to a structured approach that includes Hazard Identification, Hazard Characterization, Exposure Assessment, and Risk Characterization.
4. A Microbiological Risk Assessment should clearly state the purpose of the exercise, including the form of Risk Estimate that will be the output.
5. The conduct of a Microbiological Risk Assessment should be transparent.
6. Any constraints that impact on the Risk Assessment such as cost, resources or time, should be identified and their possible consequences described.
7. The Risk Estimate should contain a description of uncertainty and where the uncertainty arose during the Risk Assessment process.
8. Data should be such that uncertainty in the Risk Estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the Risk Estimate is minimized.
9. A Microbiological Risk Assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread.
10. Wherever possible, Risk Estimates should be reassessed over time by comparison with independent human illness data.
11. A Microbiological Risk Assessment may need reevaluation, as new relevant information becomes available.

# CDC Outbreaks and Illnesses - Food Transmission (2005-2020)



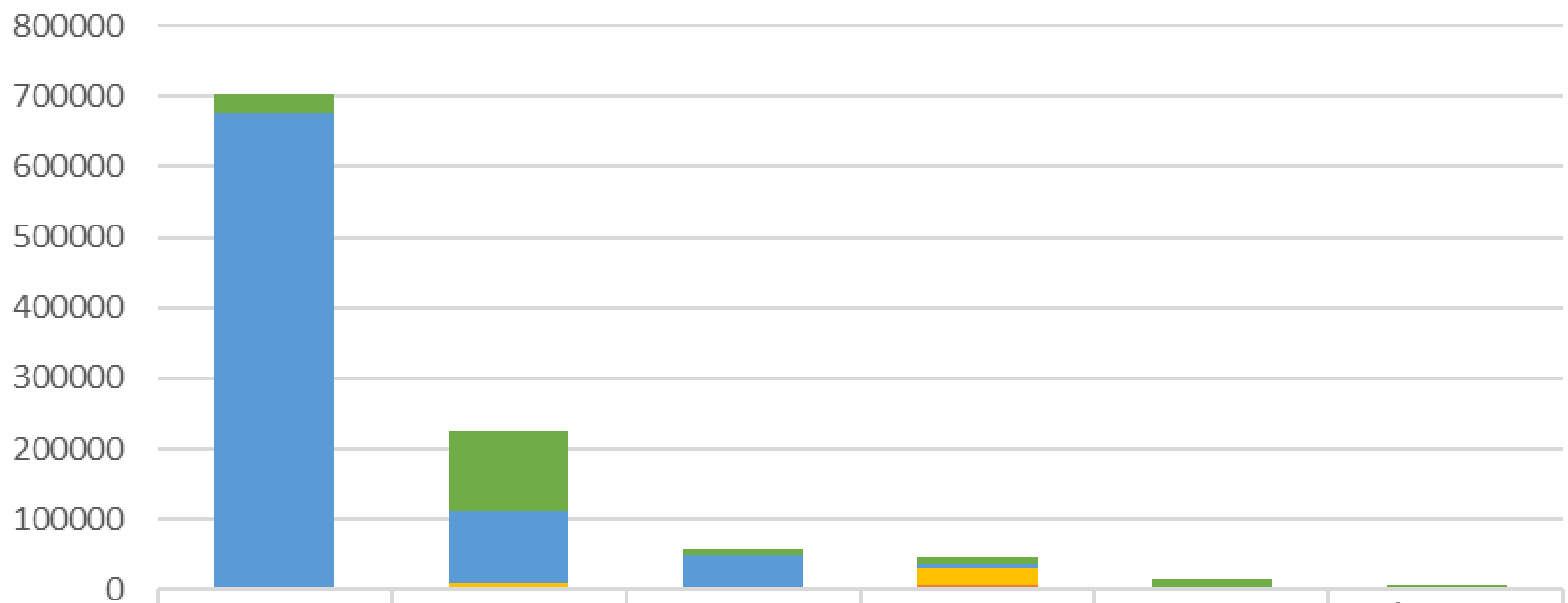

| | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Outbreaks | 964 | 1,256 | 1,098 | 1,028 | 668 | 853 | 795 | 835 | 829 | 875 | 924 | 856 | 861 | 1,054 | 874 | 303 |
| Illnesses | 19,900 | 28,881 | 21,302 | 23,133 | 13,790 | 15,868 | 14,300 | 15,002 | 13,523 | 13,360 | 15,539 | 14,446 | 15,059 | 19,991 | 11,828 | 6,072 |

# CDC Outbreaks by Transmission by Pathogen Type (2005-2020)



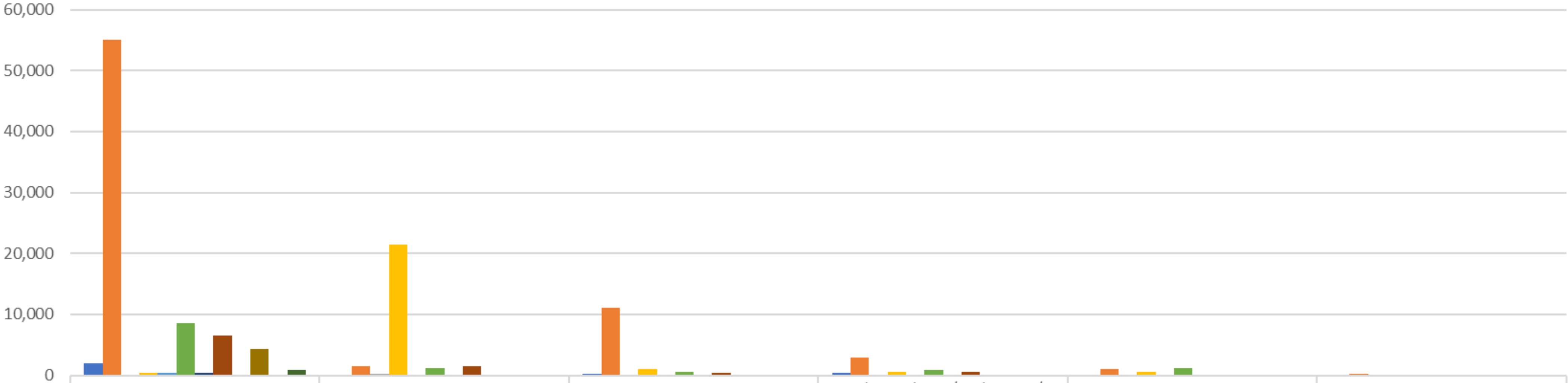

| | Person-to-person | Food | Indeterminate/Other/Unknown | Water | Animal Contact | Environmental contamination other than food/water |
|---|---|---|---|---|---|---|
| toxin | | 647 | 1 | 19 | | |
| unknown | | | | 44 | | |
| virus | 19,360 | 4,691 | 1,832 | 79 | | 58 |
| chemical | | | | 85 | | |
| parasite | 165 | 195 | 180 | 403 | 140 | 3 |
| bacteria | 1,763 | 4,947 | 1,127 | 761 | 389 | 42 |

# CDC Illnesses by Transmission by Pathogen Type (2005-2020)



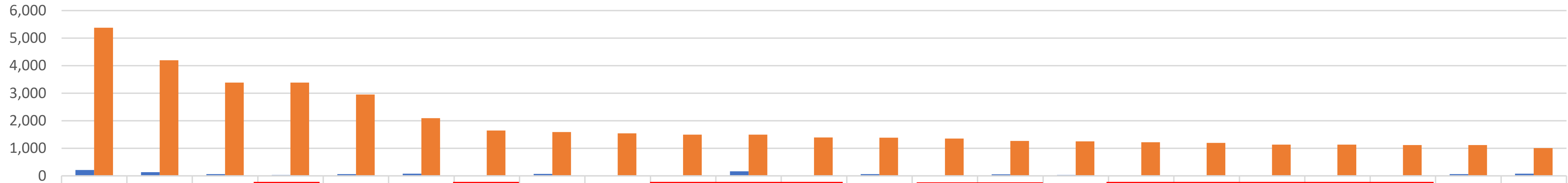

| | Person-to-person | Food | Indeterminate/Other/Unknown | Water | Animal Contact | Environmental contamination other than food/water |
|---|---|---|---|---|---|---|
| bacteria | 26,663 | 113,091 | 8,845 | 10,315 | 12,337 | 502 |
| virus | 676,277 | 102,245 | 47,758 | 5,039 | | 2,679 |
| parasite | 1,280 | 5,450 | 1,086 | 24,780 | 1,175 | 12 |
| toxin | | 2,822 | 3 | 1,810 | | |
| unknown | | | | 2,479 | | |
| chemical | | | | 2,477 | | |

# Number of Confirmed Pathogen Outbreaks and Illnesses by Transmission (2005-2020)

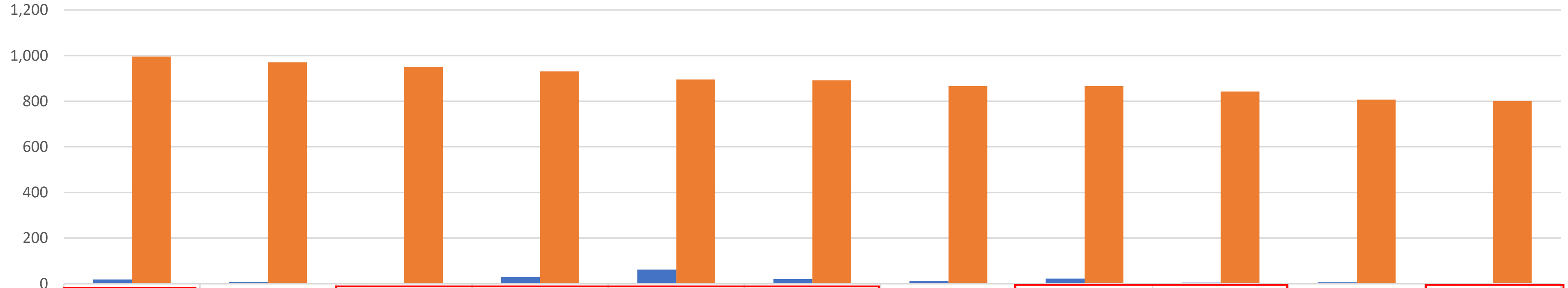



| | Food | Water | Animal | Indeterminate/ Unknown / Other | Person-to-Person | Environmental |
|---|---|---|---|---|---|---|
| Salmonella - Outbreaks | 1,949 | 7 | 231 | 395 | 159 | 15 |
| Salmonella - Illnesses | 55,104 | 1,547 | 11,106 | 2,886 | 1,038 | 259 |
| Cryptosporidium - Outbreaks | 32 | 296 | 106 | 54 | 61 | 1 |
| Cryptosporidium - Illnesses | 336 | 21,441 | 958 | 638 | 556 | 3 |
| Escherichia - Outbreaks | 459 | 41 | 62 | 153 | 148 | 8 |
| Escherichia - Illnesses | 8,503 | 1,259 | 626 | 837 | 1,112 | 112 |
| Campylobacter - Outbreaks | 349 | 30 | 52 | 109 | 19 | 8 |
| Campylobacter - Illnesses | 6,499 | 1,521 | 425 | 533 | 75 | 64 |
| Staphylococcus - Outbreaks | 123 | 1 | | 3 | 1 | |
| Staphylococcus - Illnesses | 4,276 | 8 | | 67 | 148 | |
| Listeria - Outbreaks | 94 | | | 2 | | |
| Listeria - Illnesses | 921 | | | 5 | | |

# Outbreaks, Illnesses for Food Ingredients Associated with >800 Illnesses (2005-2020) Shown on Two Scales in Upper and Lower Charts (Raw or Ready-to-Eat Foods Outlined in Red)

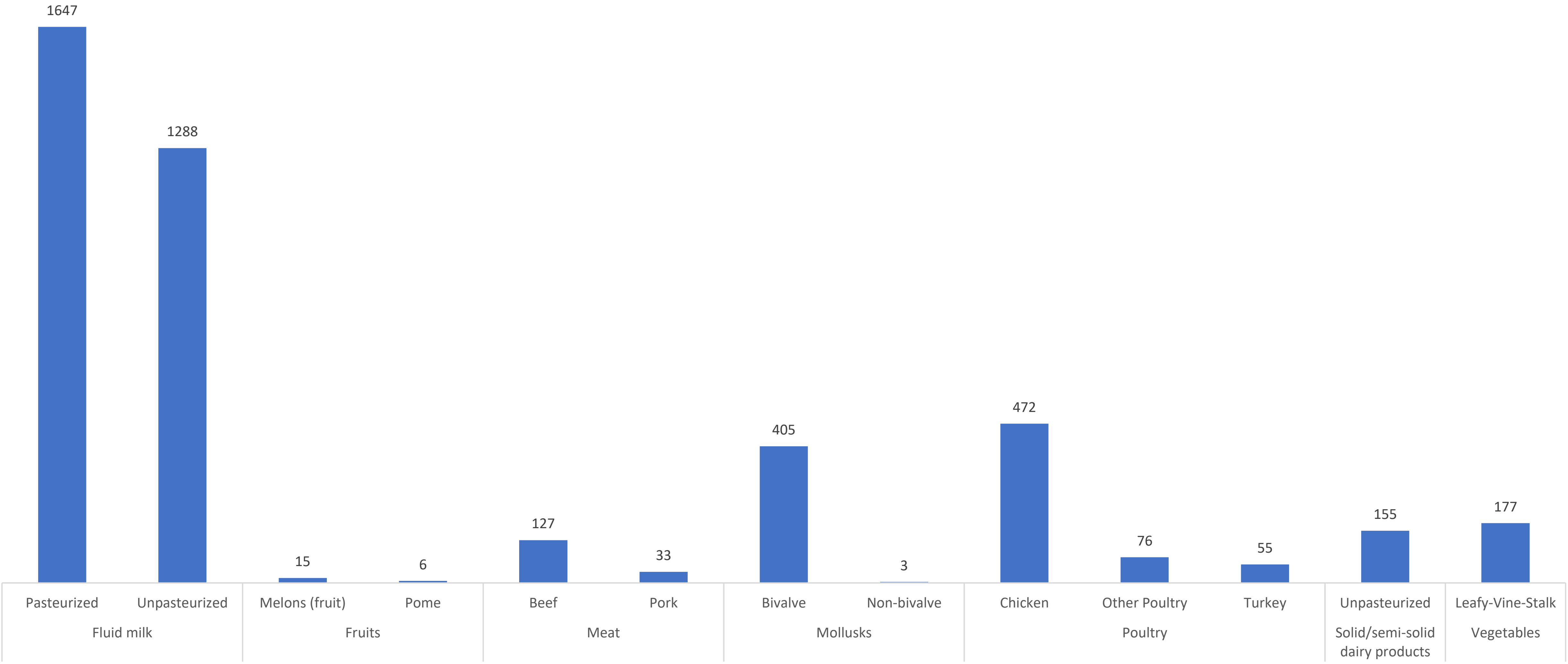



| | chicken | pork | egg | chicken salad | turkey | ground beef | other milk, pasteurized | beef | pork\|pork\|potato\|rice\|corn\|guinea pig | peppers, jalapeno\|tomato, unspecified\|peppers, serrano | oysters, raw | cucumber | multiple foods | papaya | salad, unspecified | pork, BBQ | romaine lettuce | Kratom | hummus | Red Onion | Salad mix containing lettuce and carrots | tuna | oysters |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Outbreaks | 217 | 134 | 64 | 33 | 68 | 79 | 1 | 74 | 13 | 1 | 167 | 11 | 65 | 13 | 58 | 33 | 18 | 6 | 14 | 1 | 2 | 68 | 82 |
| Illnesses | 5,373 | 4,192 | 3,383 | 3,381 | 2,952 | 2,093 | 1,644 | 1,588 | 1,547 | 1,500 | 1,497 | 1,394 | 1,386 | 1,355 | 1,268 | 1,251 | 1,221 | 1,194 | 1,138 | 1,132 | 1,118 | 1,115 | 1,006 |

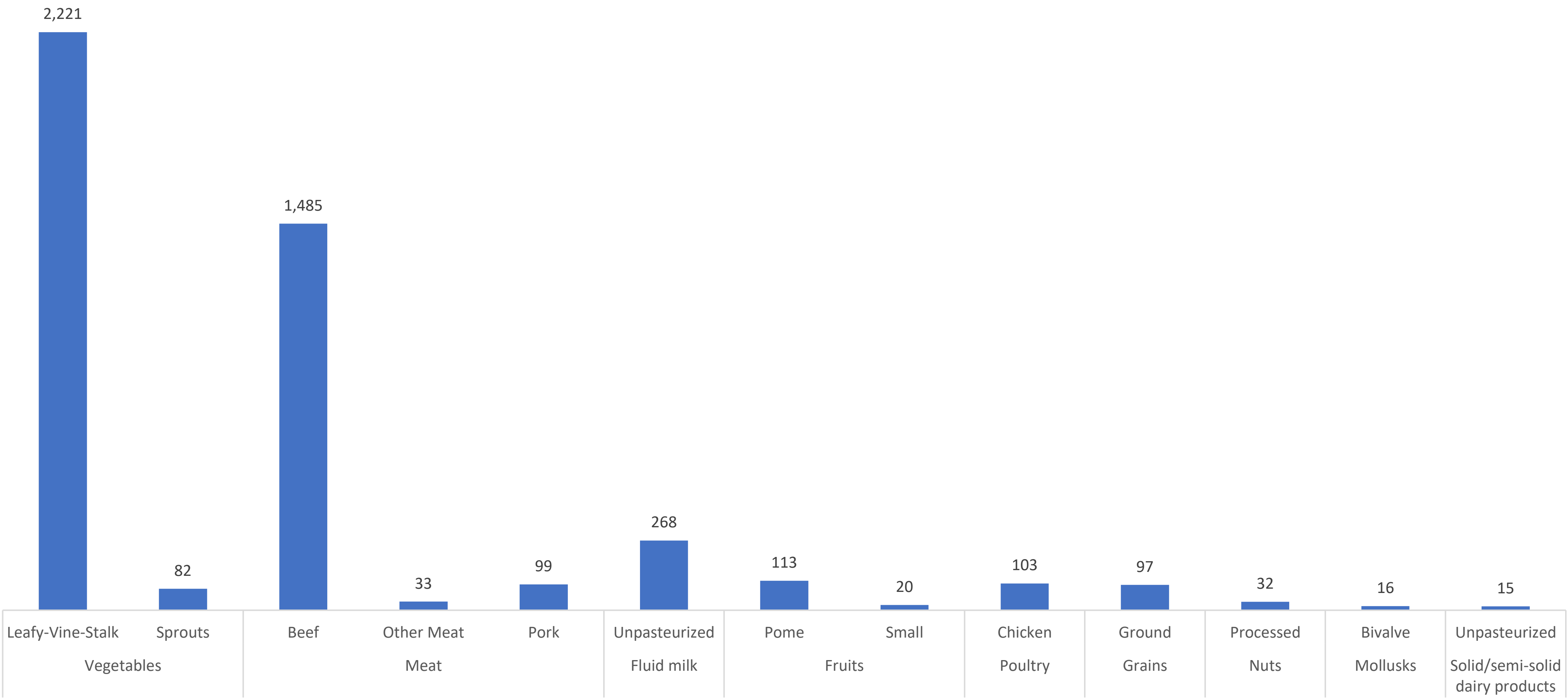



| | cantaloupe | chicken, baked | Salad mix, bagged | potato salad | milk, whole milk unpasteurized | pasta salad | turkey, baked | coleslaw | crab salad | Spices | melon |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Outbreaks | 18 | 9 | 3 | 29 | 62 | 19 | 11 | 22 | 5 | 6 | 4 |
| Illnesses | 996 | 970 | 949 | 931 | 895 | 891 | 866 | 866 | 842 | 807 | 800 |

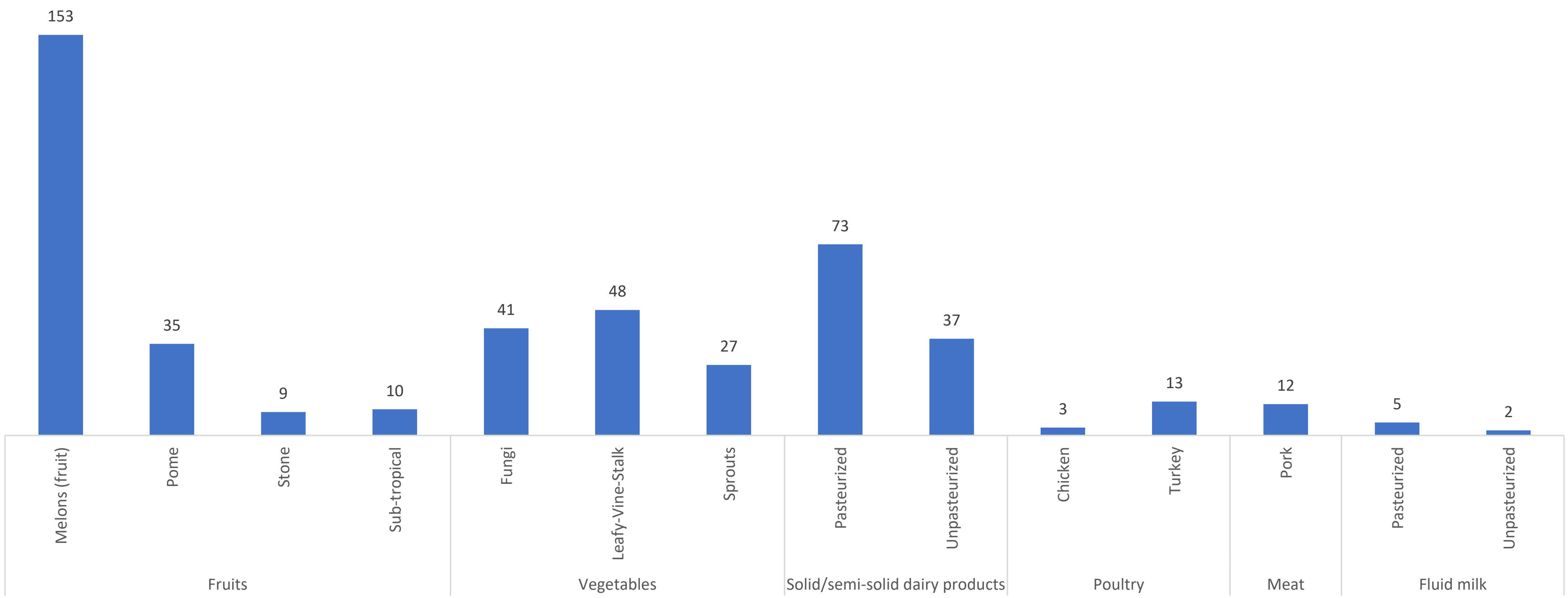
# Foodborne Campylobacteriosis Illnesses: Both IFSAC-3 and -4 Data (2005-2020)



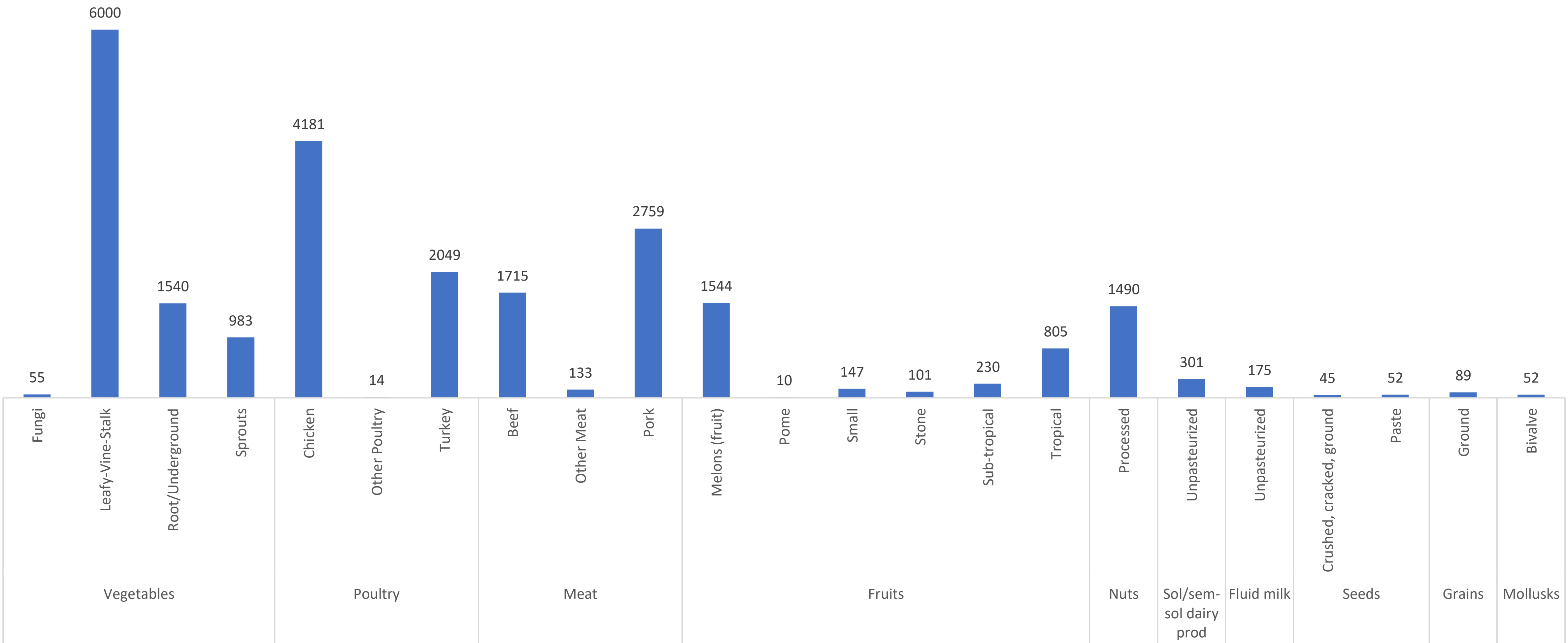
# Foodborne Pathogenic *E. coli* Illnesses: Both IFSAC-3 and -4 Data (2005-2020)



# Foodborne Listeriosis Illnesses: Both IFSAC-3 and -4 Data (2005-2020)



# Foodborne Salmonellosis Illnesses: Both IFSAC-3 and -4 Data (2005-2020)



# Illnesses by State (2005-2020): All Modes of Transmission

| <250 | 251 – 500 | 500 - 800 | 801 - 2000 | >2000 |
|---|---|---|---|---|
| Arkansas | Alabama | Connecticut (800) | Arizona | Illinois (2,461) |
| Alaska | Hawaii | Indiana (513) | California | Michigan |
| Delaware | New Mexico | Iowa | Colorado | Minnesota |
| Idaho | Georgia | Kansas | Florida | New York |
| Louisiana | Maryland | Kentucky | Maine | Oregon |
| Mississippi | Missouri (494) | Multistate | Massachusetts (1,994) | Ohio |
| New Jersey | Montana | New Hampshire | North Carolina | Pennsylvania |
| Oklahoma | Nebraska | Rhode Island | South Carolina | Wisconsin (3,152) |
| Puerto Rico | New Mexico | Washington | Tennessee (809) | |
| Republic of Palau (2) | Nevada | West Virginia | Texas | |
| South Dakota | North Dakota (278) | | | |
| Washington, DC | Utah | | | |
| Wyoming (248) | | | | |

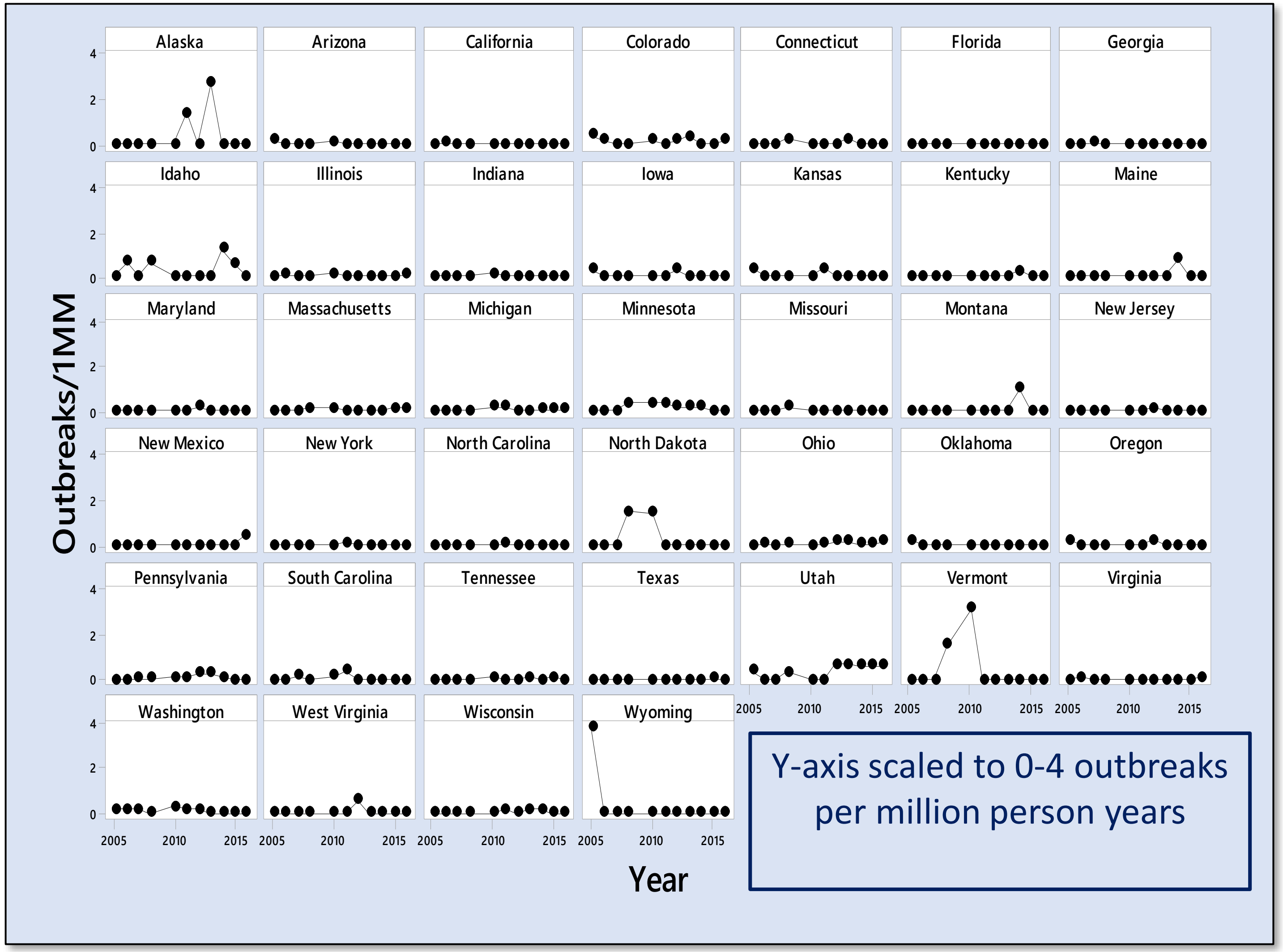
# Illnesses by State (2005-2020): Raw Cow/Goat Milk

| <10 | 10 - 23 | 25 - 47 | 51 - 58 | 94 - 198 | >300 |
|---|---|---|---|---|---|
| Florida | **Connecticut** | **Arizona** | Alaska | **California (94)** | **Utah (316)** |
| Georgia | Kansas | **Idaho** | Ohio | Multistate (101) | **Pennsylvania (322)** |
| Kentucky | Massachusetts | Indiana | New York | Wisconsin (109) | |
| **Maine** | Missouri | Illinois | Minnesota | Colorado (198) | |
| Montana | North Dakota | **Iowa** | **South Carolina** | | |
| **New Hampshire** | Oklahoma | Michigan | | | |
| **New Mexico** | Vermont | Tennessee | | | |
| North Carolina | Virginia | Texas | | | |
| **Oregon** | Wyoming | **Washington** | | | |

Text Color Code for Legal Status: **navy retail**; blue farm store; green herdshare legal; yellow no herdshare prohibition; mustard pet milk legal

# State-Level Scatterplots: No Increasing Trend for Rates of Outbreaks, Illnesses, Hospitalizations (2005 – 2016)

## Verified by Mann-Kendall Test for Trend



# Holistic Ecosystem Approaches Needed to Characterize Effects of Microbiota in Farm Environments, Feces, Milk

*dairy*

MDPI

*Article*

**Organic Farm Bedded Pack System Microbiomes: A Case Study with Comparisons to Similar and Different Bedded Packs**

**Deborah A. Neher [1,*], Tucker D. Andrews [1], Thomas R. Weicht [1], Asa Hurd [1,2] and John W. Barlow [2]** **(2022)**

**Gomes** et al. (2020). Microbiota in Dung and Milk Differ Between Organic and Conventional Dairy Farms. Frontiers in Microbiology, 11, 1746

**Wu** et al. (2019). Rumen fluid, feces, milk, water, feed, airborne dust, and bedding microbiota in dairy farms managed by automatic milking systems. Animal Science Journal, 90(3), 445-452

# Germophobia and Fear: Raw Milk Microbes **Suppress** Pathogens