Learnings from Applying RAQT to Historic Quantitative Microbial Risk Assessments (QMRAs)

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

SRA ROUND TABLE PRESENTATION, 6 DECEMBER 2022

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

Connecting RAQT Round Table with SRA 2022 Theme

- Consider some global risks and tipping points for quality analysis that might identify favorable benefit-risk outcome for decisions

- Consider policy making as a ‘**value proposition problem**’:
  - How might we identify tipping points to increase value?

- **GIVEN** policy making = *f* (science, ideology, politics, …)
  - Might applications of **RAQT** assist in distinguishing ideology and politics from science?
  - Might **RAQT** shift the balance toward evidence-based decisions and systemic change?

SRA 2022
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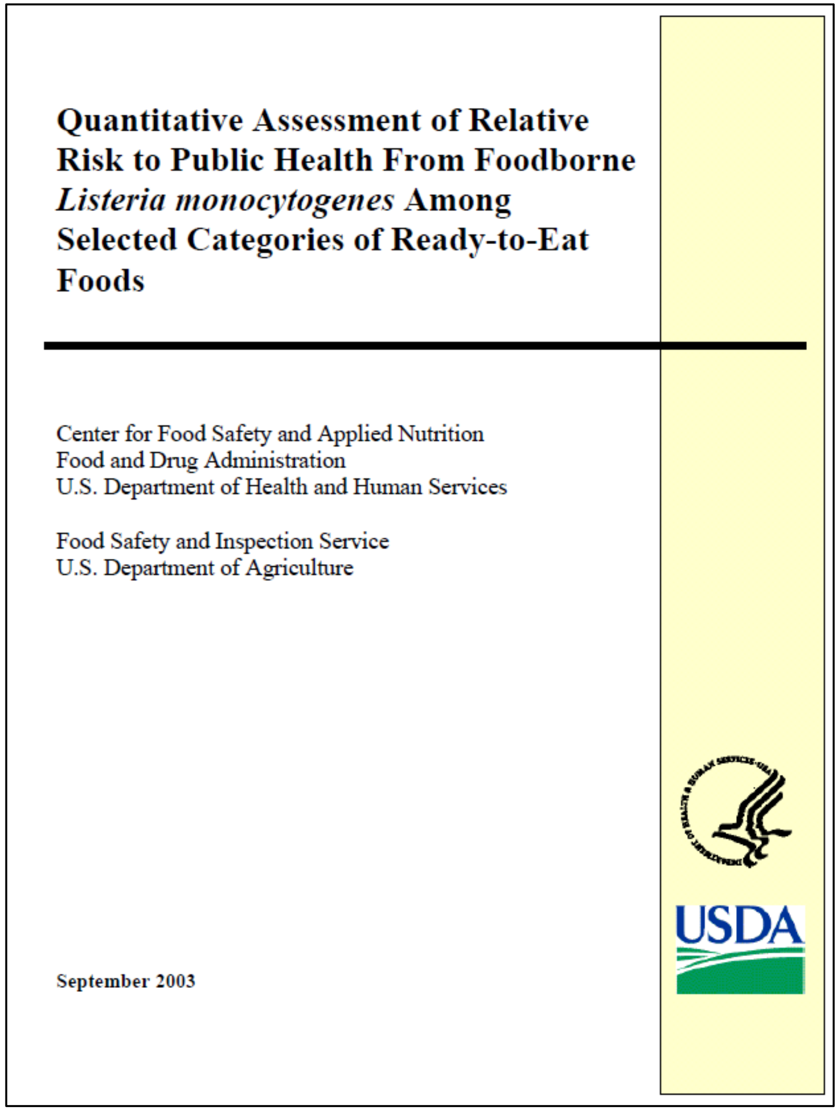
Beta Testing RAQT Tool with Two QMRAs

Why these two historic government risk assessments?

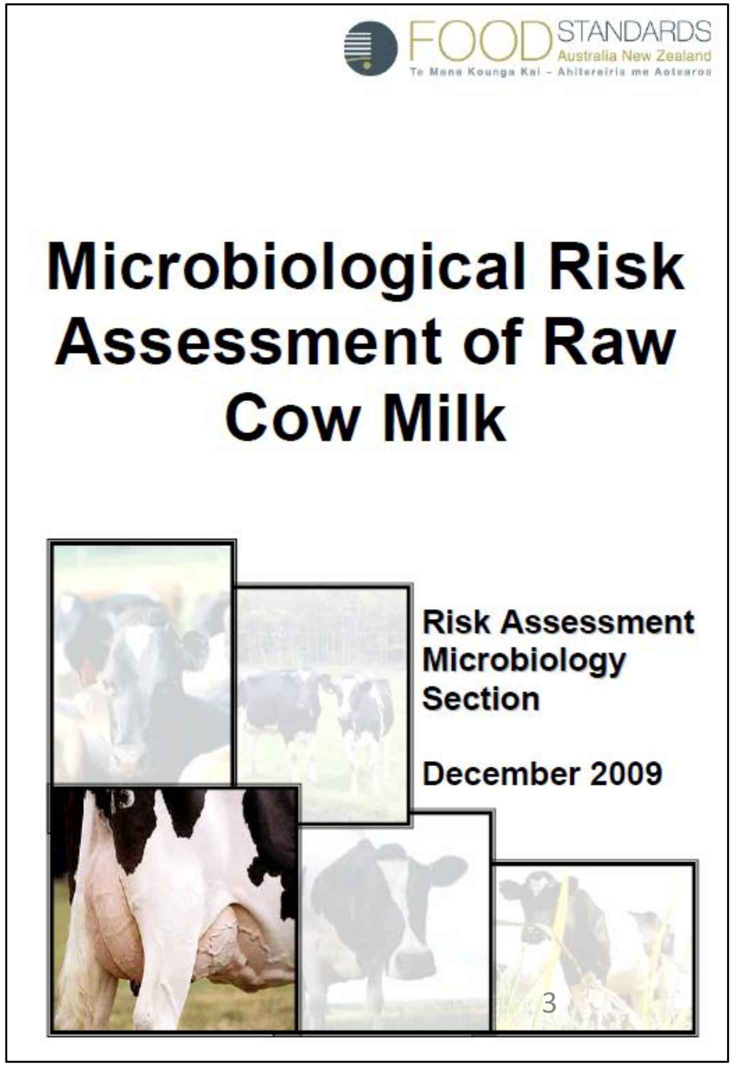
- Familiarity as peer reviewer, expert witness, consultant
- Different laws around the globe for access to raw milk
  - New Zealand and US permit access at licensed farms (or at retail, or via herd-share operations in US)
  - Australia prohibits access to raw milk except for farm families
- Ongoing project organized by Upstate NY SRA on microbiota of milks (2014 to present)


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


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

Microbiological Risk Assessment of Raw Cow Milk

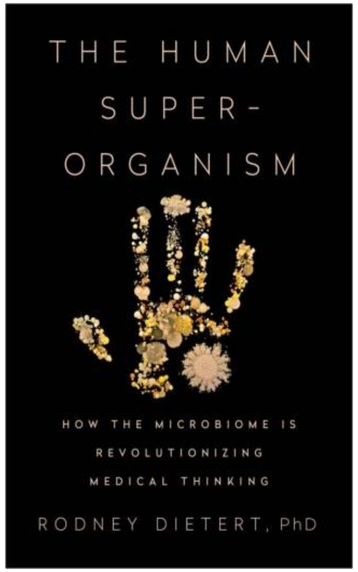
Risk Assessment Microbiology Section

December 2009

Why Raw and Pasteurized Milks?

Great interest in SRA about benefits and risks of microbiota of milks!

- **SRA 2014**: chaired session and presented on
  - *Exploring Disagreements Regarding Health Risks of Raw and Pasteurized Human and Bovine Milk*
  - Unexpected Responses: FEAR, HORROR
- **SRA 2017**: organized webinar series on microbiota of milks
  - Australia/New Zealand SRA colleague provided FSANZ 2009 QMRA for the project
  - Webinars with Cornell Emeritus Prof **Rodney Dietert** and SRA Past-President **D. Warner North** on
    - *Protecting the Human Superorganism*
    - *Preparing to Deliberate Evidence on Benefits and Risks Posed by the Microbiota of Milks*
    - Manuscript developed and published (**Dietert** et al., 2022)
      Nourishing the Human Holobiont to Reduce the Risk of Non-Communicable Diseases:
      A Cow's Milk Evidence Map Example)
- **SRA 2018** : organized round table panel on communicating evidence for benefits and risks of raw milks
- **SRA 2019**: coauthored presentation on rates of outbreaks, illnesses, and hospitalizations for CDC data on raw milk (2005 – 2016)



applied microbiology

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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

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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

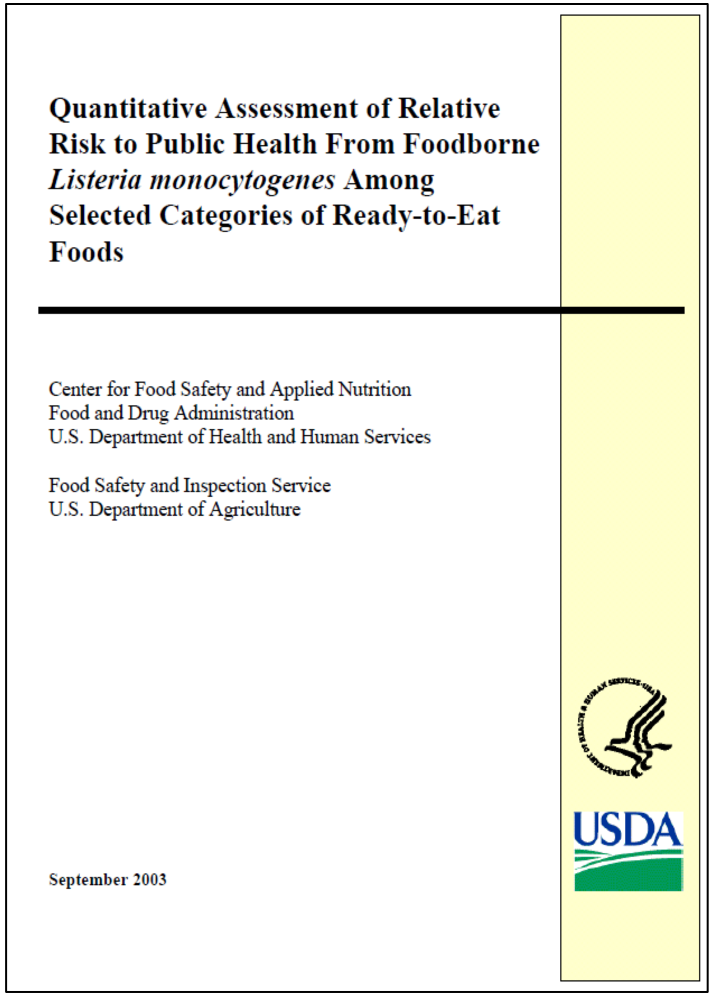
Appl. Microbiol. **2022**, Volume 2, Issue 1, 25-52

Stated Goals/Purpose for Two QMRAs

- **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**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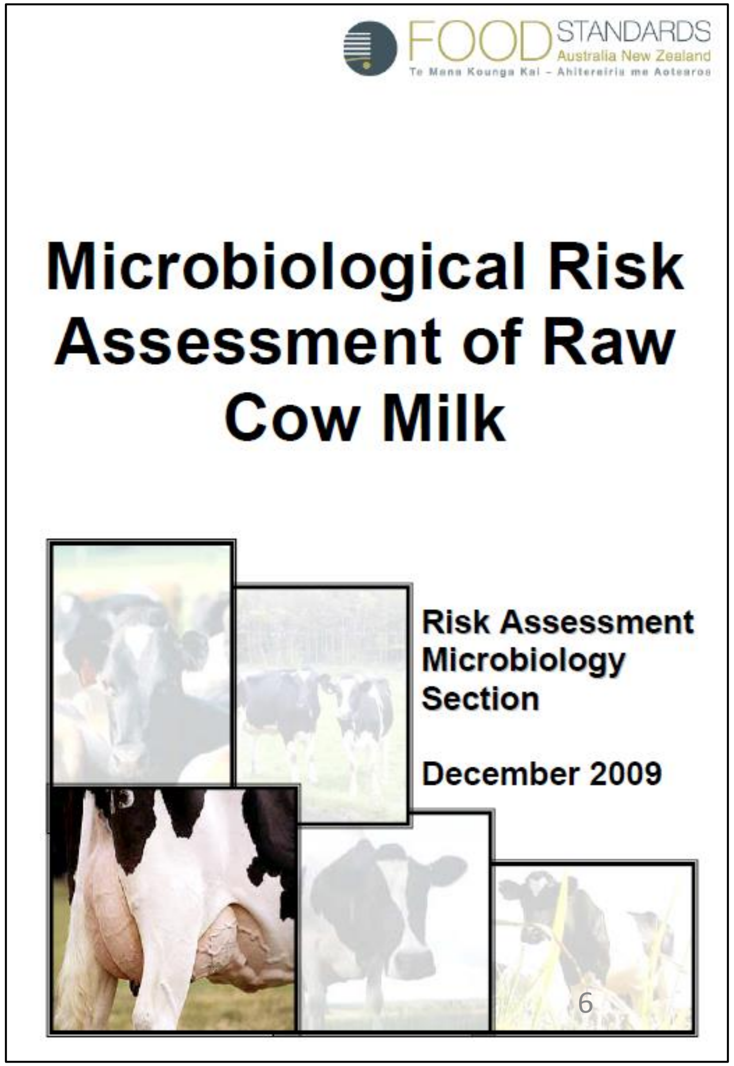


Microbiological Risk Assessment of Raw Cow Milk

Risk Assessment Microbiology Section

December 2009

RAQT as Tool to Empower Interdisciplinary Discovery, Dialogue, and Deliberation

- RAQT tool facilitated **systematic inquiry** essential to discovery and full evaluation of complex documents (QMRAs totaled ~700 pages of documentation)
- RAQT brought me to **Appendices** that shed light on evidence of potential shortfalls that merit dialogue and deliberation
- RAQT questions prompted a **series of literature searches** within and beyond my discipline (microbiology) to fill in subsequent work by QMRA authors and others that merit dialogue and deliberation

High Level Findings of Beta Testing RAQT Tool with QMRAs

1. **Extremely high percentages of shortfalls** for both QMRAs
   - ~77% shortfall rate for FSIS (additional deli meat work)
   - ~100% shortfall for FDA (milks and other RTE foods)
   - 100% shortfall rate for FSANZ
   - Evidence of bias, disconnection of these QMRA models with risk management decision-making, risk communication, and stakeholder involvement on alternative risk management scenarios

2. Some documentation of **scientific data**, but **potential tipping points** for policy appear to **favor ideology and/or politics**, not **scientific evidence**

3. Consideration of **risk-risk** or **risk-benefit tradeoffs** excluded

4. **Learnings** from recent literature searches (**bibliography** available) prompted by the RAQT questions include:
   - subsequent work and other communications by these agencies
   - subsequent work by other researchers and risk practitioners with a stake in quality risk analysis explicitly connected to alternative risk management options

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

Prioritized List of AQT Shortfalls for QMRAs

1. **AQT G3**: Clearly communicate to decision makers where limitations of knowledge (and its basis and strength) call for risk management strategies that take those limitations into account

2. AQT A10: Societal and stakeholder acceptability

3. AQT J1: List and characterize all uncertainties in one place, along with their implications

4. AQT D1: Stakeholders identified, consulted and engaged

5. AQT C2: Communication adequate between analysts, decision makers and stakeholders

RAQT Prompting Dialogue about Shifting from Managing on Fear to Evidence-Based Assessment and Analysis

Evidence Addressing Shortfall G3

Failure to clearly communicate to decision makers where **limitations of knowledge** (and its **basis** and **strength**) call for risk management strategies that take those limitations into account

- A microbiologist’s perspective on root causes
- Given those root causes, SRA audience considered how to best address this shortfall

  Procedurally? Third party reviews? Legally-Regulatory? Culture change?

- Can RAQT, or another SRA product/approach, help fix this shortfall?

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: Enhance openness to analysis and deliberation of ideology, politics, science and enable future Evidence-Based Risk Management

Root Cause: Fear and Outrage about Raw Milk in US

Published studies document urban ‘swill milk stables’ in and around large cities that contributed to high urban mortality for decades (1840s to 1920s)

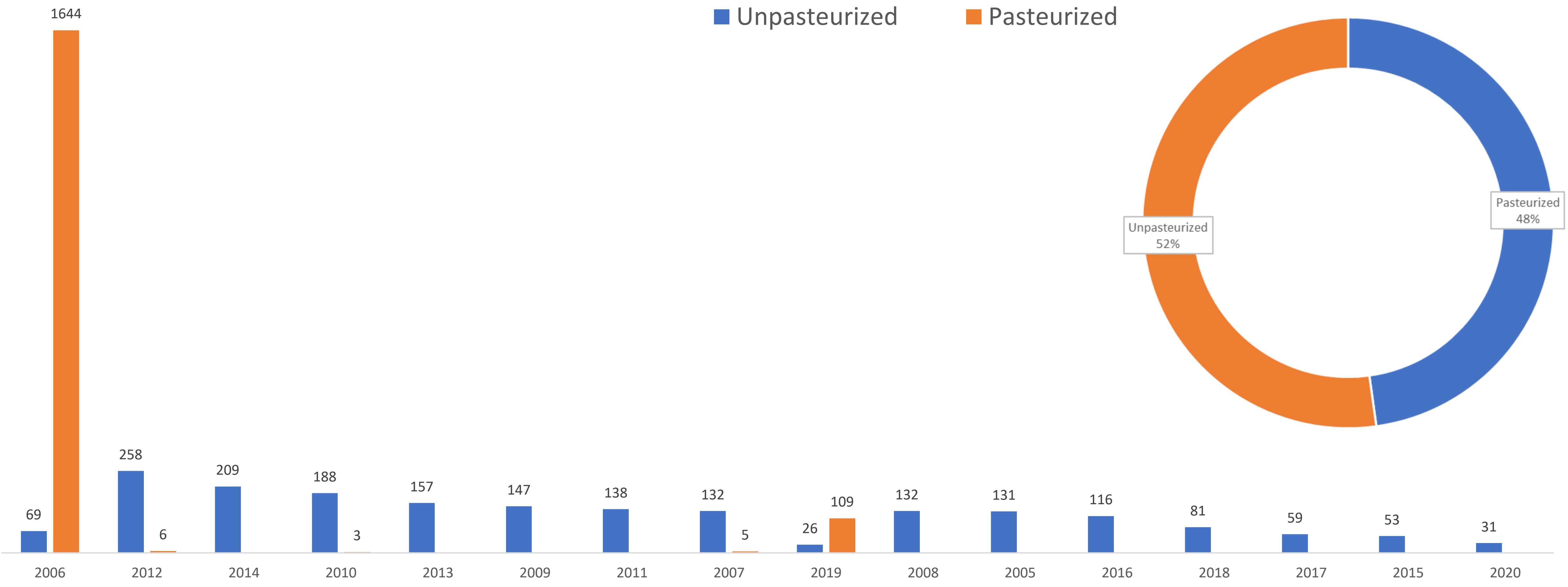
https://www.brownstoner.com/history/walkabout-the-great-milk-wars-part-1/

- 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.

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

CDC data (2005-2020) documents 3,765 illnesses for milk, 48% pasteurized

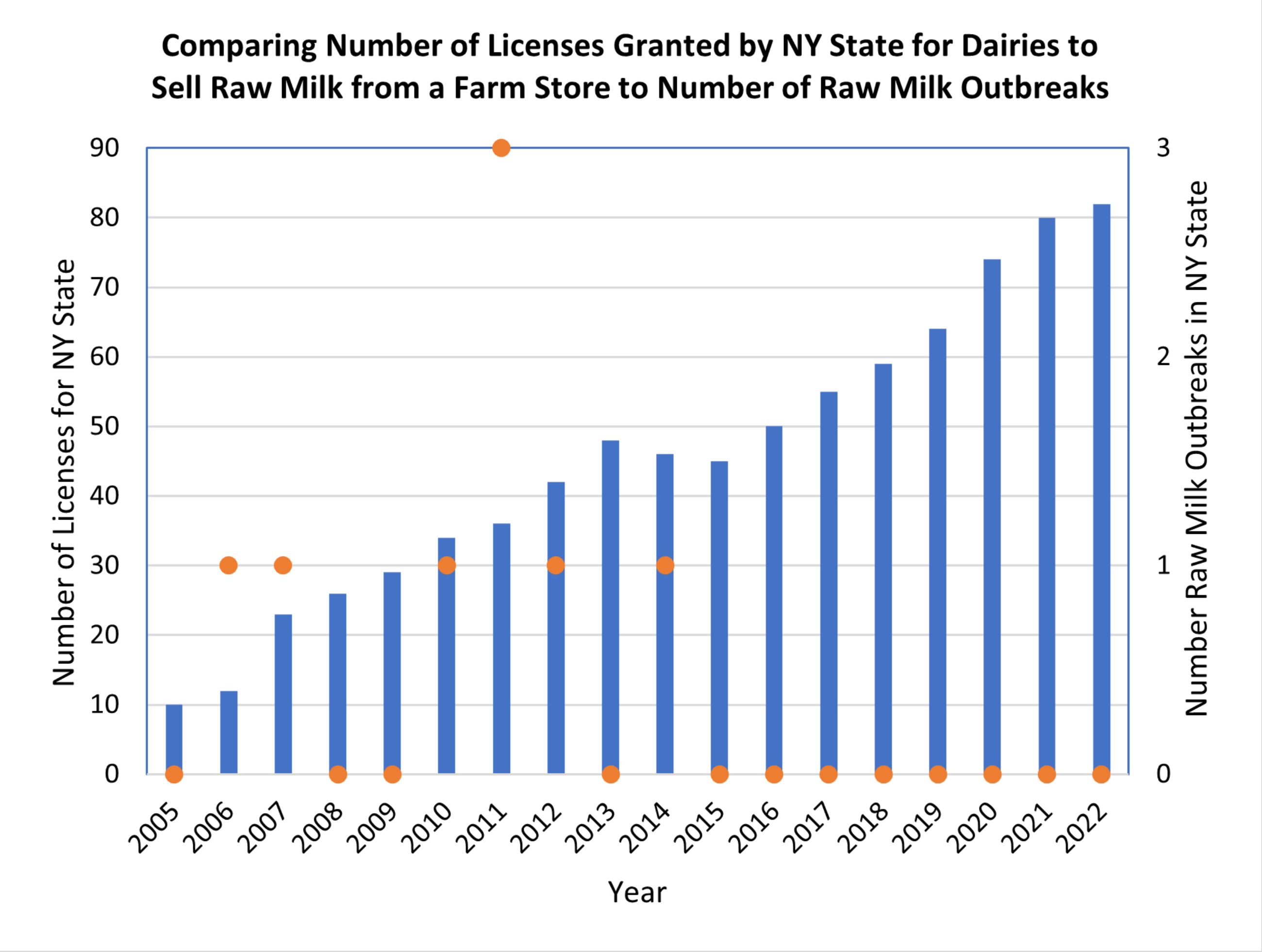


Deaths Rare for Milk in N America: in 16 Years, 6 US Deaths (4 pasteurized, 2 raw), 4 Canadian Deaths (pasteurized)

Reality for 2022: NY State Licensed 82 Raw Milk Dairies

- NY State data on numbers of licenses approved for farms selling raw milk (obtained by FOIA)

- US CDC data on 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)
  - ➢ **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 ➡
- **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
- **Consistent with 'inherently dangerous' or high-risk food?**

Country (Reference)	**Dates (State)**	***Campylobacter***	***E. coli* O157:H7 or EHECs**	***L. monocytogenes***	***Salmonella***
US Test-and-Hold Program (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

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

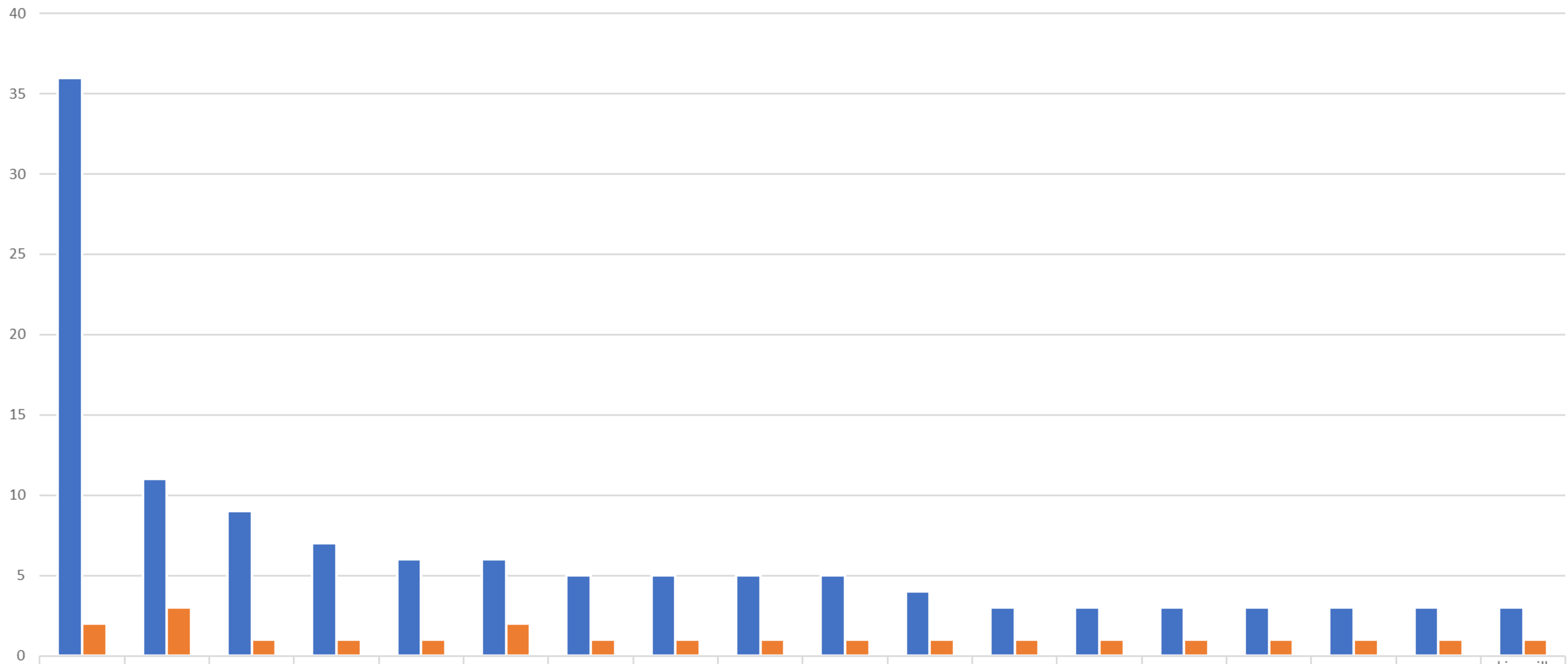
- Individual Foods (9 Dairy Foods)
  (6 cheese groupings by moisture content, +correlated w/growth potential)
  Relative Risk per Serving
  1. **Deli meats**
  2. **Pasteurized milk**
  5. Soft unripened cheese
  7. **Raw milk**
  10. **Fruits**
  12. **Vegetables**
  14. Fresh soft cheese
  15. Semi-soft 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

REALITY CHECK: Foods Associated with >2 Deaths

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

Q: Merit for FDA policy to avoid raw milk as 'inherently dangerous' food?

FSANZ Risk Management Basis: Ideology? Science?

- analysis based on unvalidated assumption that feces are predictive of presence and levels of pathogens in raw milk for Australia and New Zealand consumers

- 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

Acknowledgements

Cornell U **Emeritus Professor Rodney Dietert**
U Tasmania **Professor Tom Ross**
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SRA Past President **Dr. D. Warner North**
Former FDA Economist **Dr. Richard Williams**
Applied Risk Management Specialty Group,
Particularly **Drs. John Lathrop** and **Rob Waller**
Co-Authors of RAQT

SRA Workshop Slides Appended

COLEMAN SCIENTIFIC CONSULTING

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

SRA Workshop Slides:
RAQT Tool *beta* Testing on Microbial Risks

Prepared by Margaret E. (Peg) Coleman

For SRA Annual Meeting in Tampa, FL

Sunday, 4 December, 2022

RAQT Prompting Dialogue about Shifting from Managing on Fear to Evidence-Based Assessment and Analysis

1. Framing the analysis and its interface with decision making for societal and stakeholder acceptability (A10)

2. Stakeholders identified, consulted and engaged (D1)

3. Communication between analysts, decision makers and stakeholders productive (C2)

4. Uncertainty: listing sources, characterization, implications for risk management (J1)

5. Limitations of knowledge and its basis and strength (focused on microbiology) (G3)

1. Failure to frame the analysis and its interface with decision making to seek societal and stakeholder acceptability (A10)

RAQT *beta* Testing Findings Merit Further Analysis and Deliberation

Evidence of Ideological or Political Bias

FDA/FSIS: 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 consideration of alternatives to intentionally conservative assumptions
- 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:

- Noted significant data gaps for raw milks; applied qualitative method for goats, quantitative method (QMRA) for cows
- Unvalidated intentionally conservative assumptions (and ideology?) appeared to drive the QMRA for cows
- Assumed "little capacity for significant risk reductions" (cow)
- 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)

How to Address This Shortfall?

Shortfall 1. Failure to frame the analysis and its interface with decision making to seek societal and stakeholder acceptability (A10)

- What are the root causes?
- Given those root causes, how best "address" this shortfall?

  Procedurally? Third party reviews? Legally-Regulatory?

  Culture change? (and how could we do that?)
- Can RAQT, or another SRA product/approach, help fix this shortfall?

2. Failure to Identify, Consult, and Engage Stakeholders (D1)

RAQT *beta* Testing Findings Merit Further Analysis and Deliberation

Evidence for Stakeholder Engagement

- FDA/FSIS requested public comments on a draft assessment and a proposed risk management action plan (see backup slide). Public comments were documented in Appendices 1 and 2. Stakeholders were not systematically involved inthe decision process or the risk management implementation process. Due to the disconnect between risk assessment, communication, and management, stakeholder engagement appears inadequate.

- The FSANZ 2009 report does not cite the term ‘stakeholder’ in the 2009 report on raw cow milk, nor were stakeholders systematically involved in: framing and scoping the problem; the decision process; or the risk management implementation process. As noted for the FDA/FSIS assessment, the disconnect between risk assessment, communication, and management appears a strong barrier to stakeholder engagement.

- FSANZ had provided opportunities for public input on raw milk products included cheese, but not for raw cow milk.

How to Address This Shortfall?

Shortfall 2. Failure to Identify, Consult, Engage Stakeholders (D1)

- What are the root causes?
- Given those root causes, how best "address" this shortfall?
  Procedurally? Third party reviews? Legally-Regulatory?
  Culture change? (and how could we do that?)
- Can RAQT, or another SRA product/approach, help fix this shortfall?

3. Failure in Effective Communication Between Analysts, Decision Makers, and Stakeholders (C2)

RAQT *beta* Testing Findings Merit Further Analysis and Deliberation

Evidence for Communication between Analysts, Decision Makers, and Stakeholders

- FDA/FSIS provided opportunities for public comment on a draft assessment and a proposed risk management action plan (see backup slide). Public comments were documented in Appendices 1 and 2. Critical technical details were disclosed in Appendices, and to a limited extent in the body of the QMRA. However, due to previously described flaws in the basis of knowledge, risk communication did not adequately address established norms (e.g., ISO 31000 or IRGC methodologies). Due to the disconnect between risk assessment, communication, and management, risk communication appears inadequate.

- FSANZ 2009 did not systematically involve all stakeholders in risk analysis. Critical technical details were disclosed in Appendices, and to a limited extent in the body of the QMRA. As stated above for FDA/FSIS, due to previously described flaws in the basis of knowledge, risk communication did not adequately address established norms (e.g., ISO 31000 or IRGC methodologies). Due to the disconnect between risk assessment, communication, and management, risk communication appears inadequate.

How to Address This Shortfall?

Shortfall 3. Failure in Effective Communication Between Analysts, Decision Makers, and Stakeholders (C2)

- What are the root causes?
- Given those root causes, how best "address" this shortfall?
  Procedurally? Third party reviews? Legally-Regulatory?
  Culture change? (and how could we do that?)
- Can RAQT, or another SRA product/approach, help fix this shortfall?

4. Failure to list and characterize all uncertainties in one place, along with their implications for risk management (J1)

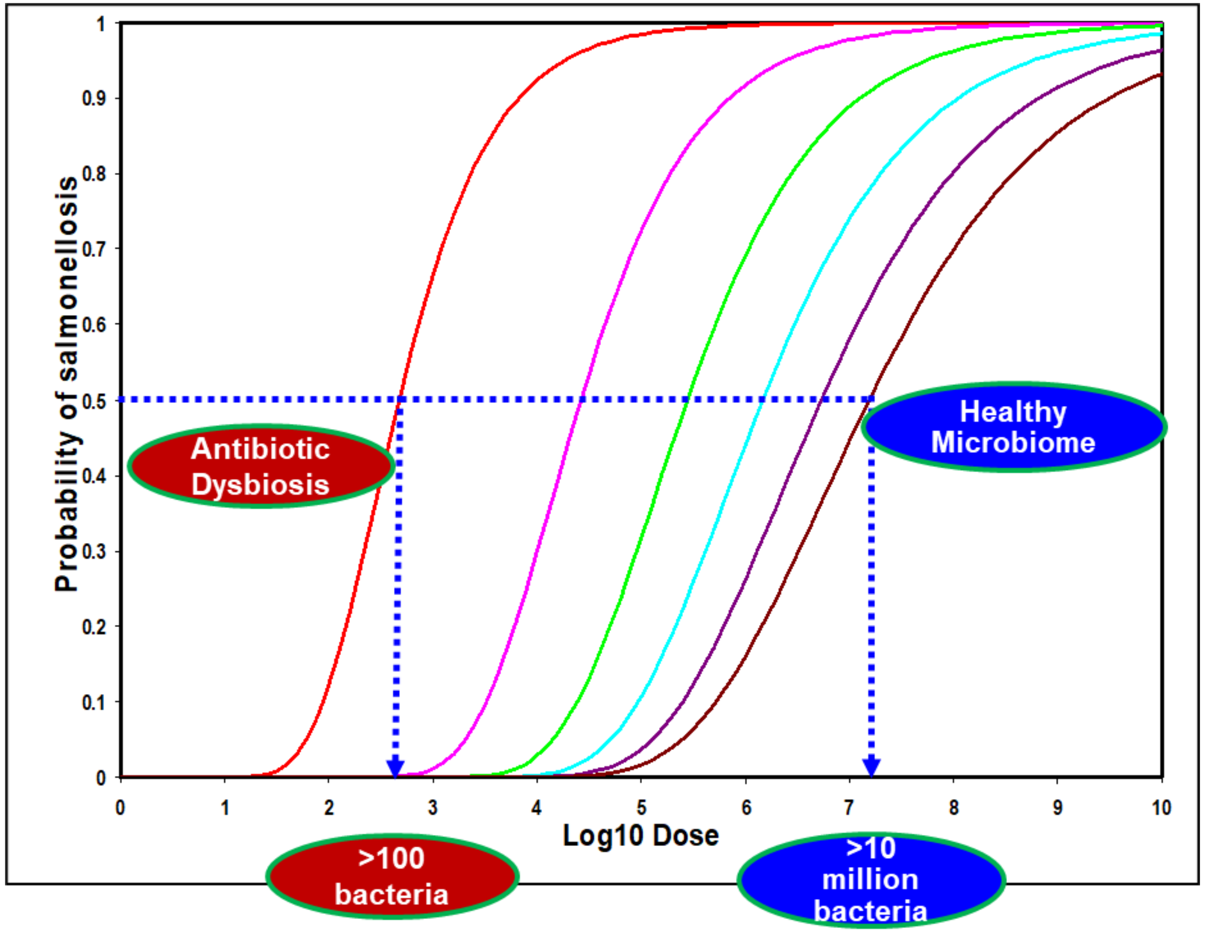
RAQT *beta* Testing Findings Merit Further Analysis and Deliberation

- Neither QMRA listed or characterized all uncertainties and their implications on risk management alternatives.
- Neither included sensitivity analysis or uncertainty analysis.
- Monte Carlo simulations were run based on assumptions and data, and bootstraps were run to estimate some sources of uncertainty.
- Some illustrations from FDA/FSIS and FSANZ QMRAs provided ABOVE

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

Uncertainty about Basis of FSANZ Conclusion

- Estimated illnesses per 100,000 servings of 540 mL to children for hypothetical scenarios (Executive Summary; Table 5)

	Farm Bulk Tank Scenario	Farm Gate Sale Scenario	Retail Purchase Scenario
Campylobacteriosis	19 illnesses	5 illnesses	<1 illness
Listeriosis	<1 illness	17 illnesses	170 illnesses
Pathogenic *E. coli*/EHEC	16 illnesses	49 illnesses	97 illnesses
Salmonellosis	17 illnesses	55 illnesses	153 illnesses

- Although FSANZ simulated three scenarios above using conservative assumptions, in reality, farm gate sale and retail sale of raw milk are prohibited in Australia. The only legal consumers of raw milk in Australia are dairy farm families. New Zealand permits farm gate sales for licensed farms. No independent epidemiologic data appears to validate the simulations of <1 to 19 illnesses per 100,000 servings.

- **Conclusion 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)

Extremely Low Percentage Positives from Raw Milk for 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)

Q: Where is the evidence for raw milk as an inherently dangerous food?

Ideology, Politics, or Science?
Is Pasteurization a Silver Bullet ensuring Safety?

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.

Key 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*."

This conclusion is not supported by the data and analysis. Ideology?

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.

How to Address This Shortfall?

Shortfall 4. Failure to list and characterize all uncertainties in one place, along with their implications for risk management (J1)

- What are the root causes?
- Given those root causes, how best “address” this shortfall?
  Procedurally? Third party reviews? Legally-Regulatory?
  Culture change? (and how could we do that?)
- Can RAQT, or another SRA product/approach, help fix this shortfall?

5. Failure to clearly communicate to decision makers where limitations of knowledge (and its basis and strength) call for risk management strategies that take those limitations into account (G3)

RAQT *beta* Testing Findings Merit Further Analysis and Deliberation

- FDA/FSIS provided information on basis of knowledge for foods and food groups, largely in appendices. The strength of the basis of knowledge is poor and misleading for some foods and food groups. What is missing for decision makers is context that relates benefits, risks, and costs of interventions for a ubiquitous pathogen (Lm) causing a very rare disease (severe listeriosis). The basis of knowledge is not linked to decision making alternatives. Imposing 'zero tolerance' for Lm in RTE foods (declared adulterated based solely on pathogen presence) merits wider deliberation (**Farber** et al., **2021**), particularly when thresholds for innate resistance to illness are feasible (**Buchanan** et al., **2017**; **Rahman** et al., **2016**, **2018**, **2020**). The application of 'zero tolerance' for Lm appears to reflect **ideology**, not **science**.

- FSANZ relied on unvalidated assumptions since no data for exposure assessment to Australian consumers was (or currently is) available. Although significant data gaps were noted for both exposure assessment and dose-response assessment, no studies have been undertaken to fill those data gaps. FSANZ communicated their belief in a 2021 memo that data would not change their risk assessment. This statement is consistent with **ideology tipping policy *away from science***.

Appendices Illuminate Selective Pooling:
Potential Ideological Bias by FDA/FSIS

- Pooling of studies for different foods within a group may be justified
- Justification for pooling significantly different growth data for raw and pasteurized milks that were recognized as separate foods?
  - **Northolt** et al., (1988): *Lm* grew **faster** in **pasteurized** milk (0.407 cfu/g*day) than raw milk (0.085 cfu/g*day) at refrigeration temperatures
  - **Northolt** attributed this effect to the thermal suppression of the natural microbiota present in raw milk during pasteurization
  - FDA/FSIS's decision to pool disparate, significantly different rates of growth and apply one 'average' growth rate (0.257 cfu/g*day) to both raw and pasteurized milk was not justified

Q: Is inappropriate pooling evidence of ideological bias, ensuring raw milk risk was overestimated and pasteurized milk risk was underestimated?

Independent Re-Assessment for Raw Milk Risk

FDA/FSIS (2003) versus Update by **Latorre et al. (2011)**

Pasteurized Milk

- 90.8 deaths per year (**high** risk)
- 10^{-9} per serving or 1 fatal case in 1,000,000,000 exposures at selected doses (**moderate** risk)

Unpasteurized Milk

FDA/FSIS:

- 3.1 deaths per year (**moderate** risk)
- $7x10^{-9}$ per serving or 7 fatal cases in 1,000,000,000 exposures at selected doses (**high** risk)

Latorre:

- ~$2x10^{-15}$ per serving or 2 cases in 1,000,000,000,000,000 exposures (**very low** risk)

Evidence for Updating Incorrect Assumptions about Pasteurized Milk

- FDA/FSIS averaged growth rate for **pasteurized** AND **unpasteurized** milk (0.257 cfu/g/day)

- Independent academic researchers (**Stasiewicz** et al, **2014**) found that Lm growth **increased** with **increasing pasteurization temperature**, consistent with **Northolt** et al. **(1988)**
  - 0.503 cfu/mL/day for milk treated at 162° (F)
  - 0.562 cfu/mL/day for milk treated at 180° (F)

- Subsequent systematic review (**Sebastianski** et al., **2022**) found that Lm was "more likely to be the causative agent in **pasteurized** milk outbreaks (p<0.001) and proportions of **hospitalizations and deaths** were **higher** in **pasteurized** than in unpasteurized outbreaks (p<0.01)"

Q: Is ideology that pasteurized milk poses zero risk tipping the balance against quality analysis?

44

Summary of FSANZ 2009 Assumptions, Data, Modeling

1. **No data** were available from Australia for **pathogen prevalence and levels** in raw milk or raw milk **consumption volumes and frequencies** for farm families in 2009
   - **European Food Safety Authority (EFSA)** scientific opinion on raw milk risks (2015)
     - Acknowledged FSANZ assessment but determined data insufficient to estimate risk for EU rather than rely on assumptions
   - FSANZ relied on intentionally conservative assumptions for their 2009 analysis and funded no research to fill significant data gaps by 2021 (FSANZ Chief Executive Officer Mark Booth)

2. **Pathogen prevalence and levels** in **raw milk** were either:
   - inferred from a monitoring study in Scotland (Fenlon et al., 1995) on Lm
   - extrapolated from pathogen prevalence and levels in **feces** for *Campylobacter*, pathogenic *E. coli*/EHEC/STEC, *Salmonella*

Exclusion of Available Growth Studies by FSANZ

- FSANZ cited FDA/FSIS, but excluded citation of:
  - finding that both pasteurized and raw milk were high risk
  - **Northolt** et al. (1988) who reported growth of Lm was significantly **higher** in **pasteurized** than raw milk

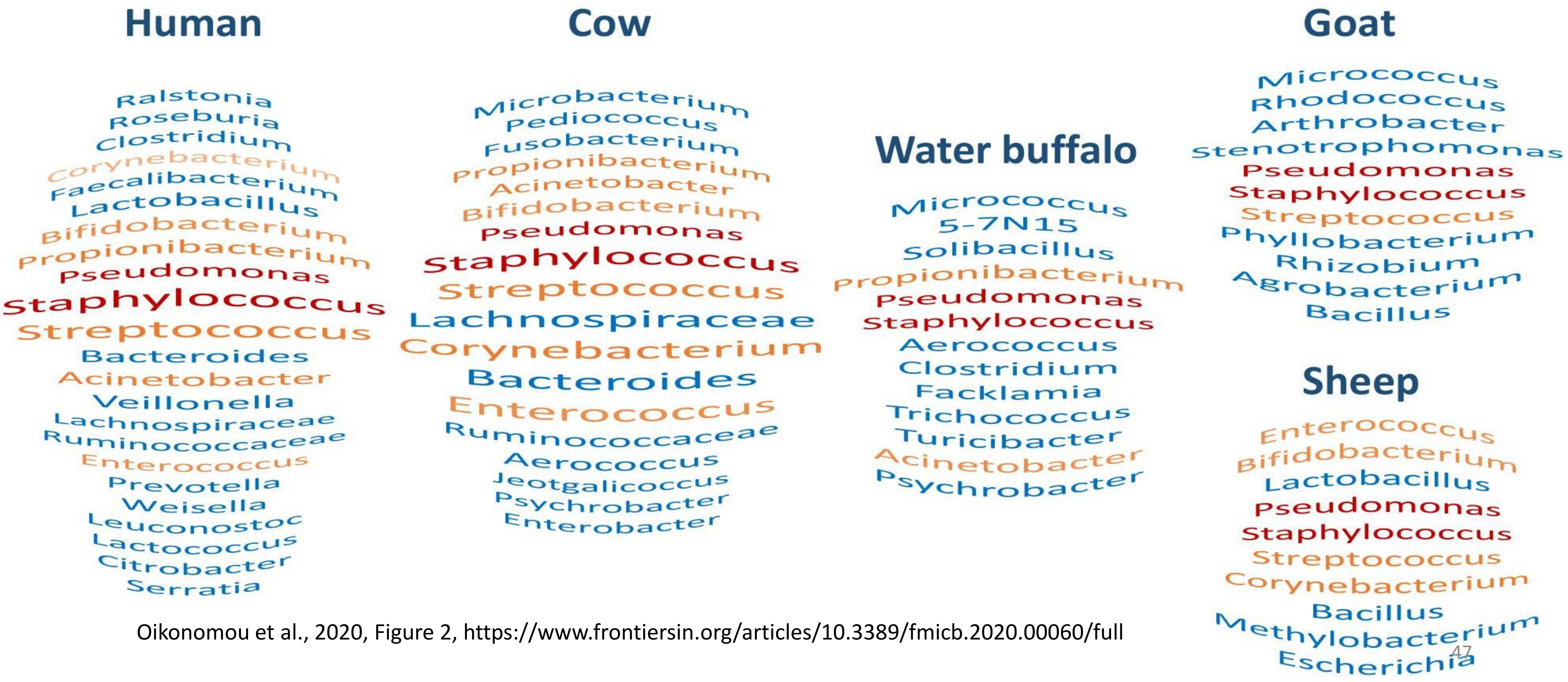
- FSANZ cited of a dissertation (Salter, 1998) but excluded the primary study
  - **Wang** et al. (1997) reported that *E. coli* O157:H7 grew **significantly faster** in **pasteurized** milk than raw milk

- Excluded effects of competition by the natural microbiota of foods to reduce the growth of pathogens mentioned in other studies below and based growth estimates on 'purposely conservative' (fail-safe) models of non-pathogenic *E. coli* in culture broth
  - **Coleman** et al. (2003a,b)
  - **Northolt** et al. (1988)
  - **Salter**, Ross, McMeekin (1998)
  - **Wang** et al. (1997)

Q: Is ideology that pasteurized milk poses zero risk tipping the balance against quality analysis?

Need to Incorporate Recent Evidence on Milk Microbiota that Outcompetes Pathogens

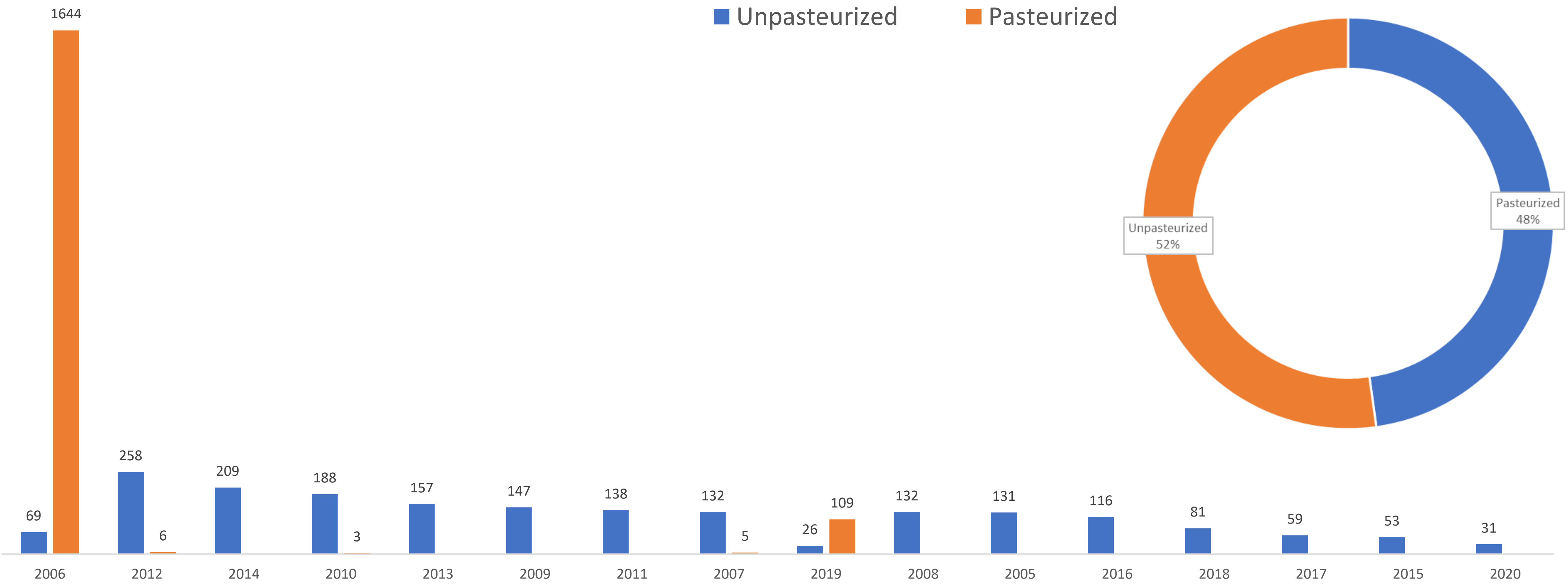
Consider synergistic multi-hurdle options including microbial competition of pathogens with dense diverse natural microbiota of milks



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

Evidence for Updating Incorrect Assumptions about Pasteurized Milk

CDC data (2005-2020) documents 3,765 illnesses for milk, 48% pasteurized



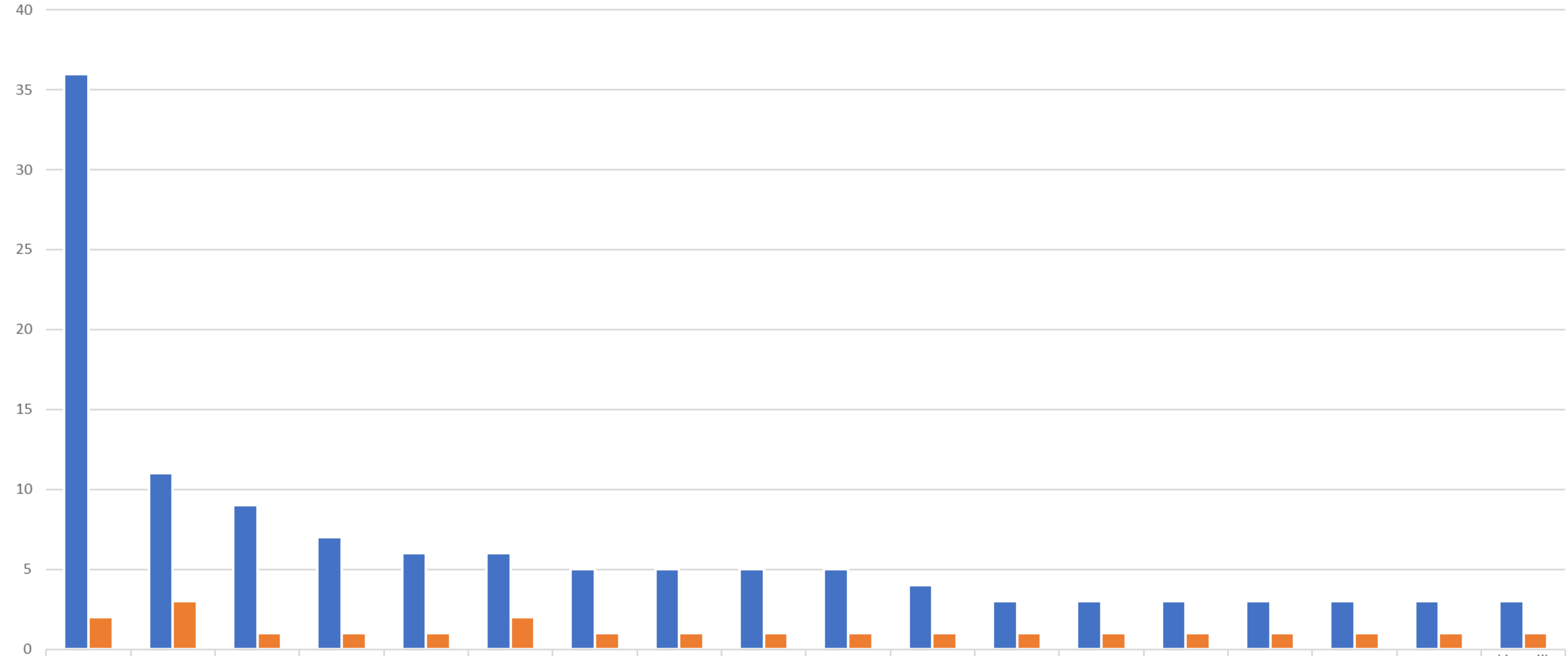
Deaths rare for milk: 5 US deaths in 16 years (2 raw, 3 pasteurized), 4 Canadian deaths (pasteurized)

Reality Check: Foods Associated with Outbreaks Reporting 1 or 2 Deaths
(CDC NORS, 2005-2020)

<table>
<tr><td>ackawi cheese, pasteurized|chives cheese, pasteurized</td><td>cucumber</td><td>ice cream, commercial (pasteurized)</td><td>oysters, raw</td><td>soup, jambalaya</td></tr>
<tr><td>alfalfa sprouts|alfalfa sprout seeds</td><td>dairy products (unspecified)</td><td>Italian-style deli meats</td><td>oysters|oysters, raw</td><td>steak, sirloin</td></tr>
<tr><td>artisinal soft cheese, unpasteurized</td><td>deli products</td><td>latin style soft cheese</td><td>papaya</td><td>stone fruit</td></tr>
<tr><td>avocado, unspecified</td><td>eggs</td><td>leafy greens</td><td>peaches</td><td>strawberries</td></tr>
<tr><td>beef</td><td>eggs, hard boiled</td><td>lettuce</td><td>peppers, jalapeno|tomato, unspecified|peppers, serrano</td><td>taco combo meal</td></tr>
<tr><td>beef|latin style soft cheese</td><td>eggs, over-easy</td><td>lettuce based salads, unspecified</td><td>pork</td><td>tahini</td></tr>
<tr><td>beets</td><td>Enoki Mushroom</td><td>meatballs|roast beef</td><td>pork rib tips</td><td>tomato</td></tr>
<tr><td>blue-veined cheese, unpasteurized</td><td>fermented fish heads</td><td>melon</td><td>potato</td><td>turkey</td></tr>
<tr><td>cantaloupe</td><td>fruit salad</td><td>melon, unspecified</td><td>pre-packaged leafy greens</td><td>turkey, baked</td></tr>
<tr><td>cantaloupe|ground beef, unspecified</td><td>gravy</td><td>Mexican cheese (queso fresco and/or other)</td><td>pre-packaged salad</td><td>turkey, unspecified</td></tr>
<tr><td>carrot juice, pasteurized</td><td>ground beef</td><td>Mexican style cheese, pasteurized</td><td>pureed food diet</td><td>venison</td></tr>
<tr><td>carrots|oil|onion|oregano|tomato|pepper, chili|vinegar</td><td>ground beef, other</td><td>milk (unpasteurized)</td><td>queso fresco, pasteurized</td><td>vine-stalk e.g., tomato</td></tr>
<tr><td>Cheese (unspecified)</td><td>ground beef|lettuce|sprouts</td><td>milk|milk (pasteurized)</td><td>rice</td><td>watermelon</td></tr>
<tr><td>cheese, pasteurized</td><td>ground turkey, unspecified</td><td>mung bean sprouts</td><td>salmon, unspecified</td><td rowspan="3">whale</td></tr>
<tr><td>chicken salad</td><td>herbal tea</td><td>nachos and cheese</td><td>sausage, pork</td></tr>
<tr><td>chicken|steak</td><td>home-canned vegetable, unspecified</td><td>other cheese, pasteurized</td><td>smoked fish</td></tr>
<tr><td>country style deli ham</td><td>hummus</td><td>oysters</td><td>soft cheese</td><td></td></tr>
</table>

REALITY CHECK: Foods Associated with >2 Deaths

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

Q: Merit for FDA policy to avoid raw milk as ‘inherently dangerous’ food?

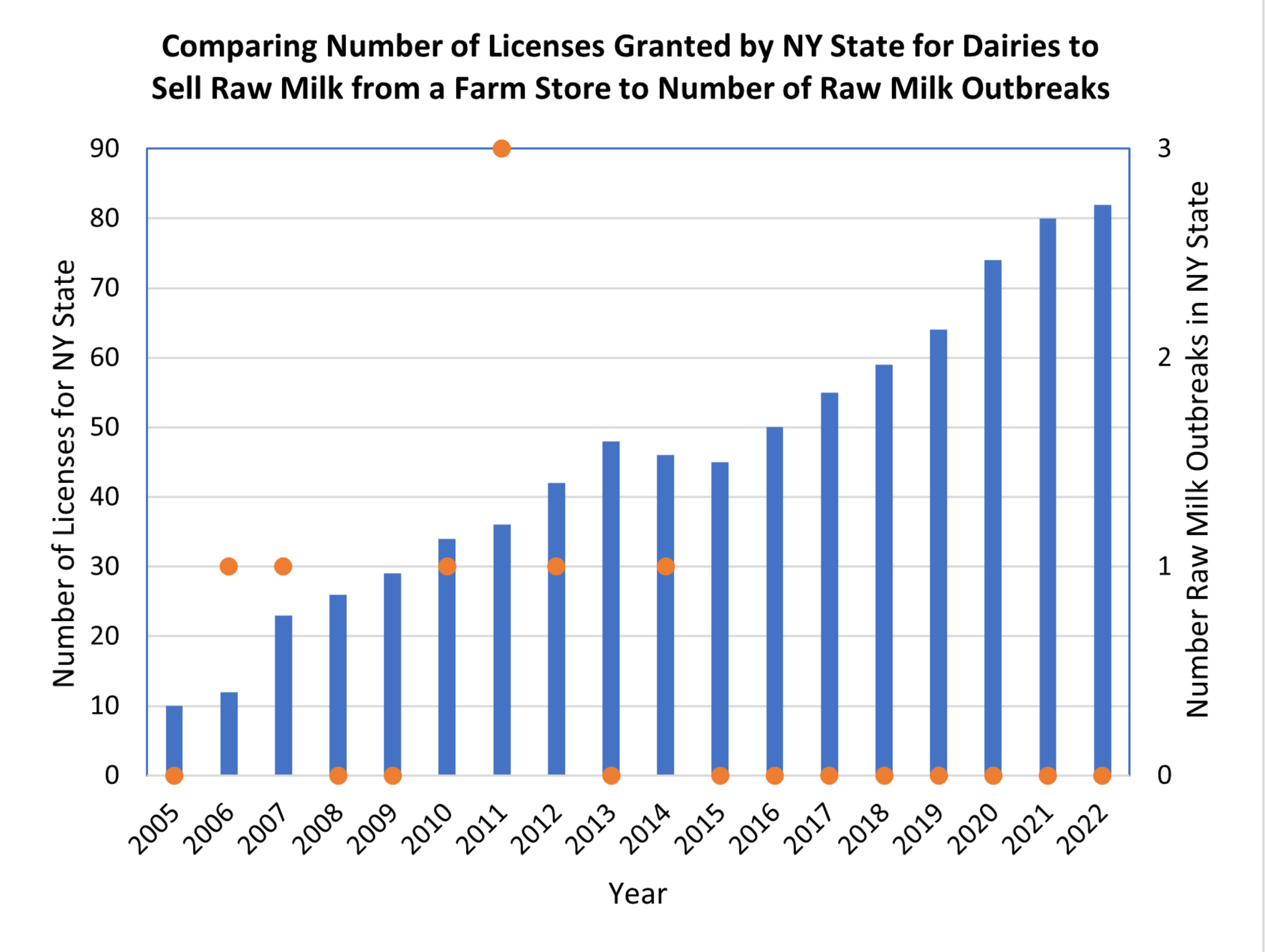
Main Microbial Hazards in Raw Milk

(European Food Safety Authority, 2015; NY State Monitoring)

- *Brucella melitensis* (US herds vaccinated)
- ***Campylobacter* spp.**
- *Mycobacterium bovis* (US herds vaccinated)
- ***Salmonella* spp.**
- **Shiga Toxin-producing *E. coli* (STEC)**
- Tick Borne Encephalitis Virus (TBEV) (No US cases or outbreaks)

Absent from the EFSA list:

Listeria monocytogenes



How to Address These Shortfalls?

5. Failure to clearly communicate to decision makers where limitations of knowledge (and its basis and strength) call for risk management strategies that take those limitations into account (G3)

- What are the root causes?
- Given those root causes, how best “address” this shortfall?

  Procedurally? Third party reviews? Legally-Regulatory?

  Culture change? (and how could we do that?)
- Can RAQT, or another SRA product/approach, help fix this shortfall?

Backup Slides

One Source of Fear and Outrage about Raw Milk in US

Urban ‘swill milk stables’ in and around large cities (1840s to 1920s)

- Unhealthy and dying cows in urban ‘dairies’, starved then fed hot distillery waste
- ‘Swill milk’ adulterated (added water, flour, chalk, plaster of Paris, sugars, salts, or bicarbonate of soda) to mask thin bluish appearance
- ‘Swill milk’ recognized as contributor to high urban mortality
- Wealthy urban families could afford to buy ‘country milk’ produced by healthy pasture raised cows
- NY City Milk law passed in 1862/1864 made sale of ‘any impure, adulterated, or unwholesome milk’ a misdemeanor and outlawed feeding cows on food that would produce unwholesome milk in Manhattan
- Brooklyn protected swill milk businesses decades longer

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

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

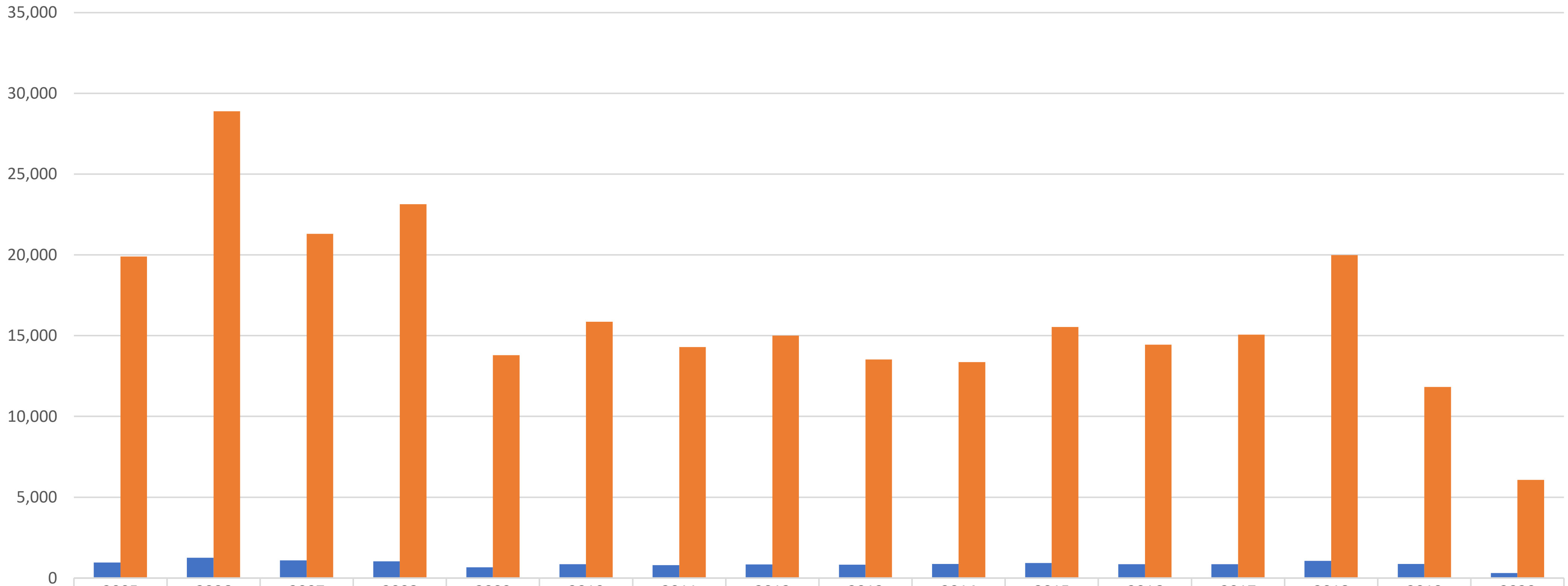
(Dietert et al., 2022)

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)

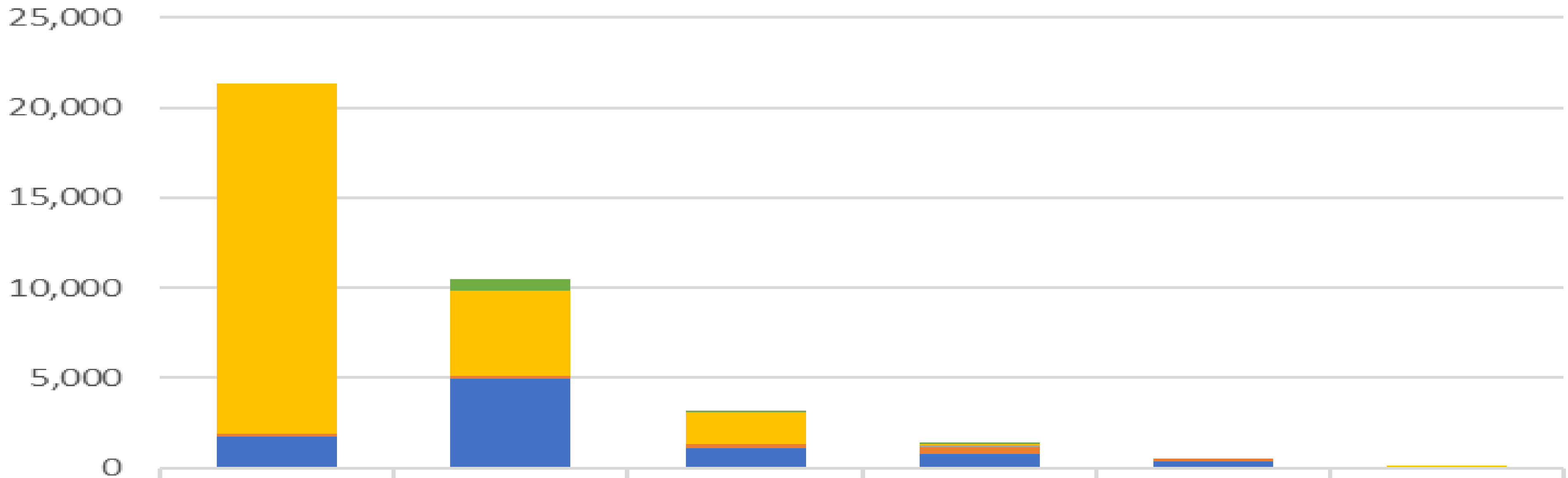
- Organizing Protest in the Changing City: Swill Milk and Social Activism in New York City, 1842–1864. (Egan, 2005)
- From Swill Milk to Certified Milk: Progress in Cow's Milk Quality in the 19th Century. (Obladen, 2014)
- Mortality Differentials between Rural and Urban Areas of States in the Northeastern 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)

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



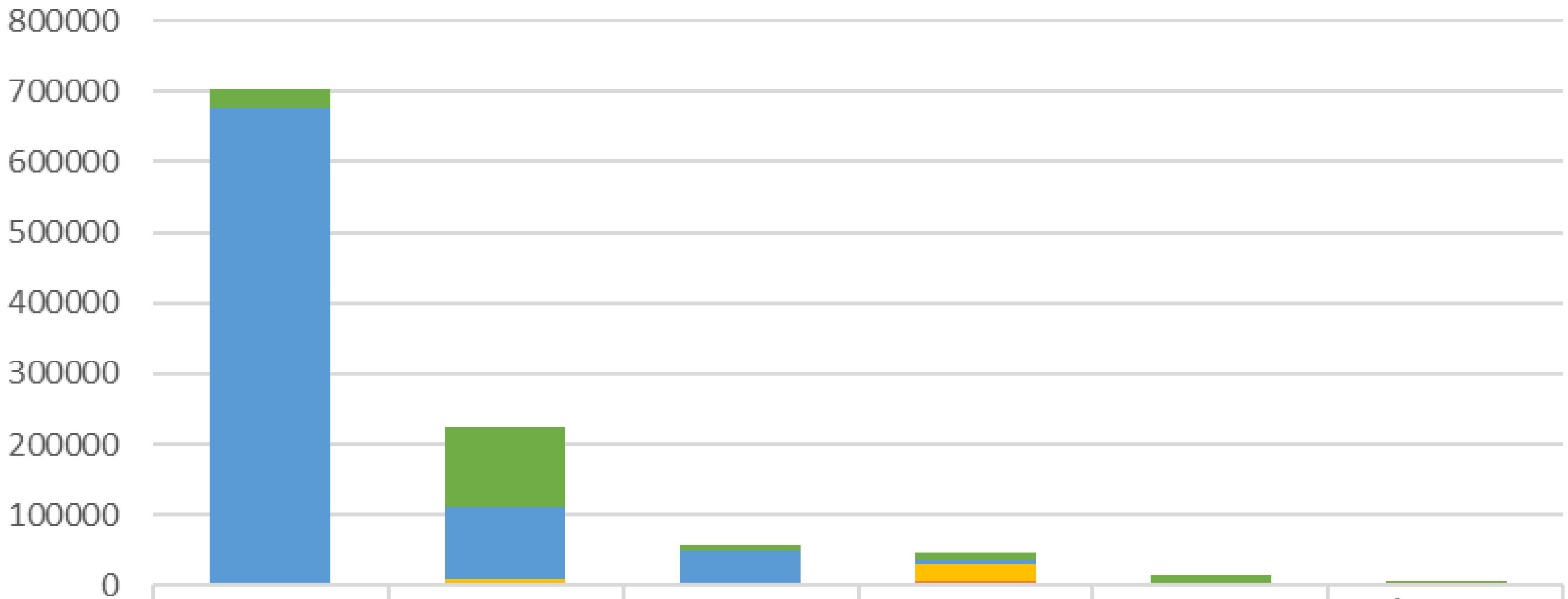
	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Outbreaks	964	1,256	1,098	1,028	668	853	795	835	829	875	924	856	861	1,054	874	303
Illnesses	19,900	28,881	21,302	23,133	13,790	15,868	14,300	15,002	13,523	13,360	15,539	14,446	15,059	19,991	11,828	6,072

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



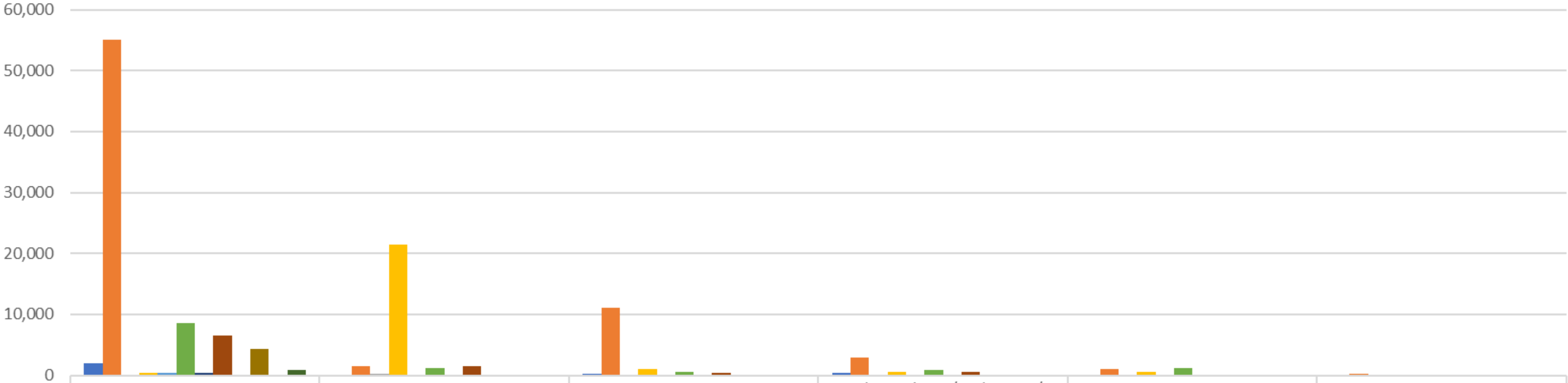
	Person-to-person	Food	Indeterminate/Other/Unknown	Water	Animal Contact	Environmental contamination other than food/water
toxin		647	1	19		
unknown				44		
virus	19,360	4,691	1,832	79		58
chemical				85		
parasite	165	195	180	403	140	3
bacteria	1,763	4,947	1,127	761	389	42

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



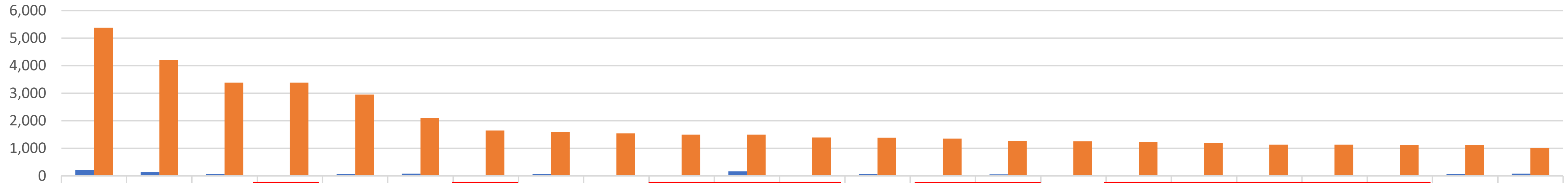
	Person-to-person	Food	Indeterminate/Other/Unknown	Water	Animal Contact	Environmental contamination other than food/water
bacteria	26,663	113,091	8,845	10,315	12,337	502
virus	676,277	102,245	47,758	5,039		2,679
parasite	1,280	5,450	1,086	24,780	1,175	12
toxin		2,822	3	1,810		
unknown				2,479		
chemical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

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



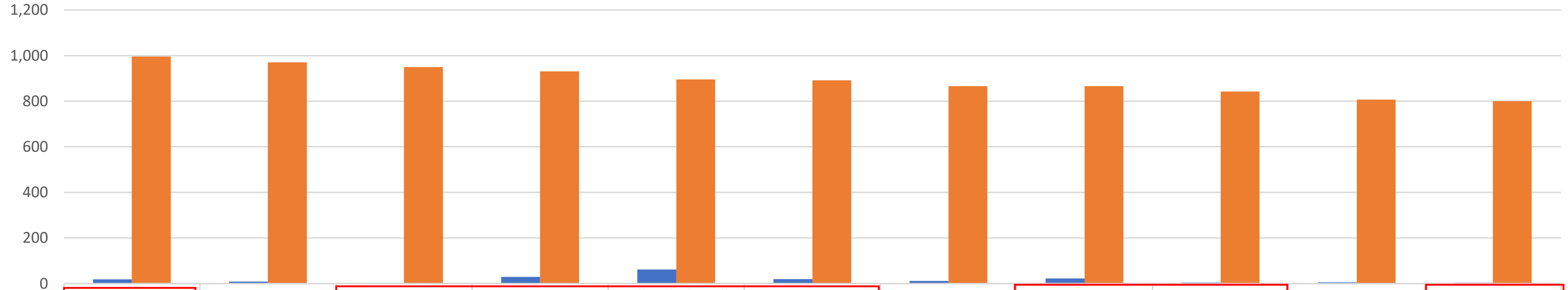
	Food	Water	Animal	Indeterminate/ Unknown / Other	Person-to-Person	Environmental
Salmonella - Outbreaks	1,949	7	231	395	159	15
Salmonella - Illnesses	55,104	1,547	11,106	2,886	1,038	259
Cryptosporidium - Outbreaks	32	296	106	54	61	1
Cryptosporidium - Illnesses	336	21,441	958	638	556	3
Escherichia - Outbreaks	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)



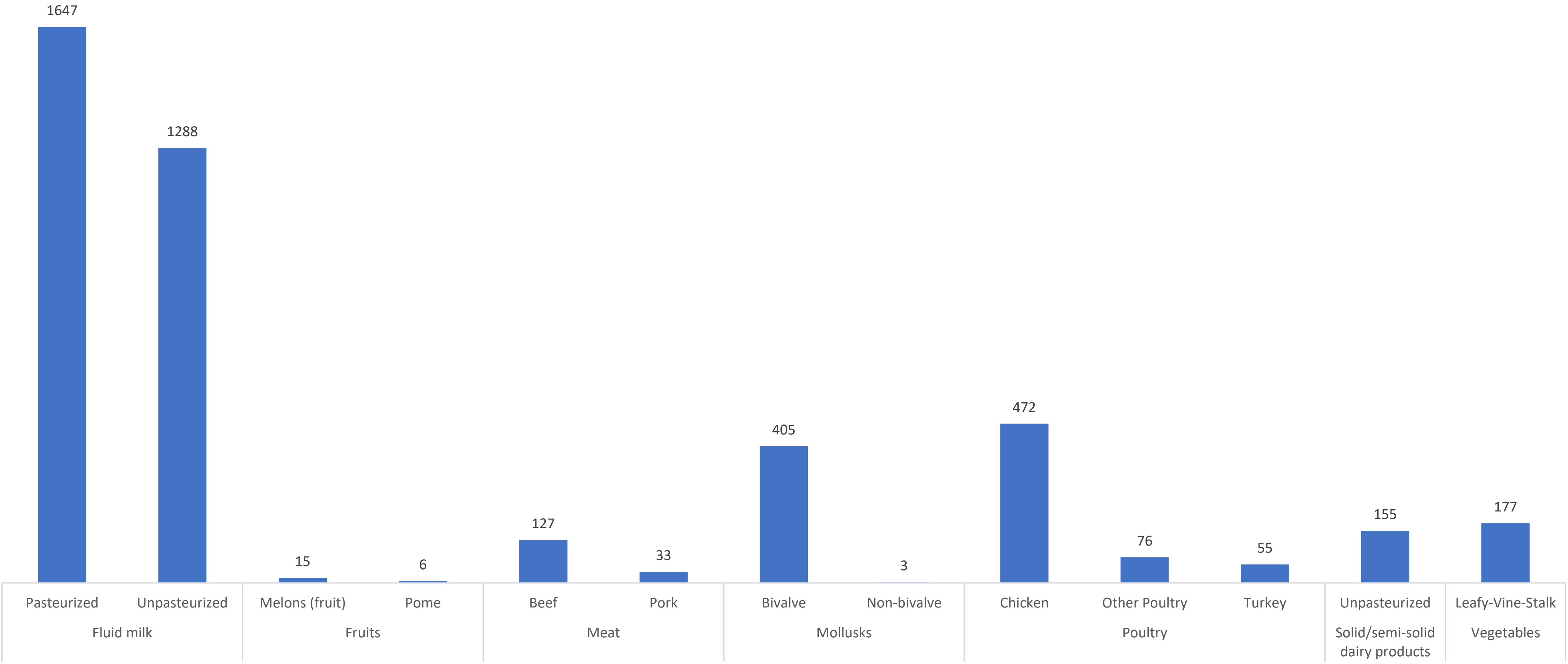
	chicken	pork	egg	chicken salad	turkey	ground beef	other milk, pasteurized	beef	pork|pork|potato|rice|corn|guinea pig	peppers, jalapeno|tomato, unspecified|peppers, serrano	oysters, raw	cucumber
Outbreaks	217	134	64	33	68	79	1	74	13	1	167	11
Illnesses	5,373	4,192	3,383	3,381	2,952	2,093	1,644	1,588	1,547	1,500	1,497	1,394

	multiple foods	papaya	salad, unspecified	pork, BBQ	romaine lettuce	Kratom	hummus	Red Onion	Salad mix containing lettuce and carrots	tuna	oysters
Outbreaks	65	13	58	33	18	6	14	1	2	68	82
Illnesses	1,386	1,355	1,268	1,251	1,221	1,194	1,138	1,132	1,118	1,115	1,006

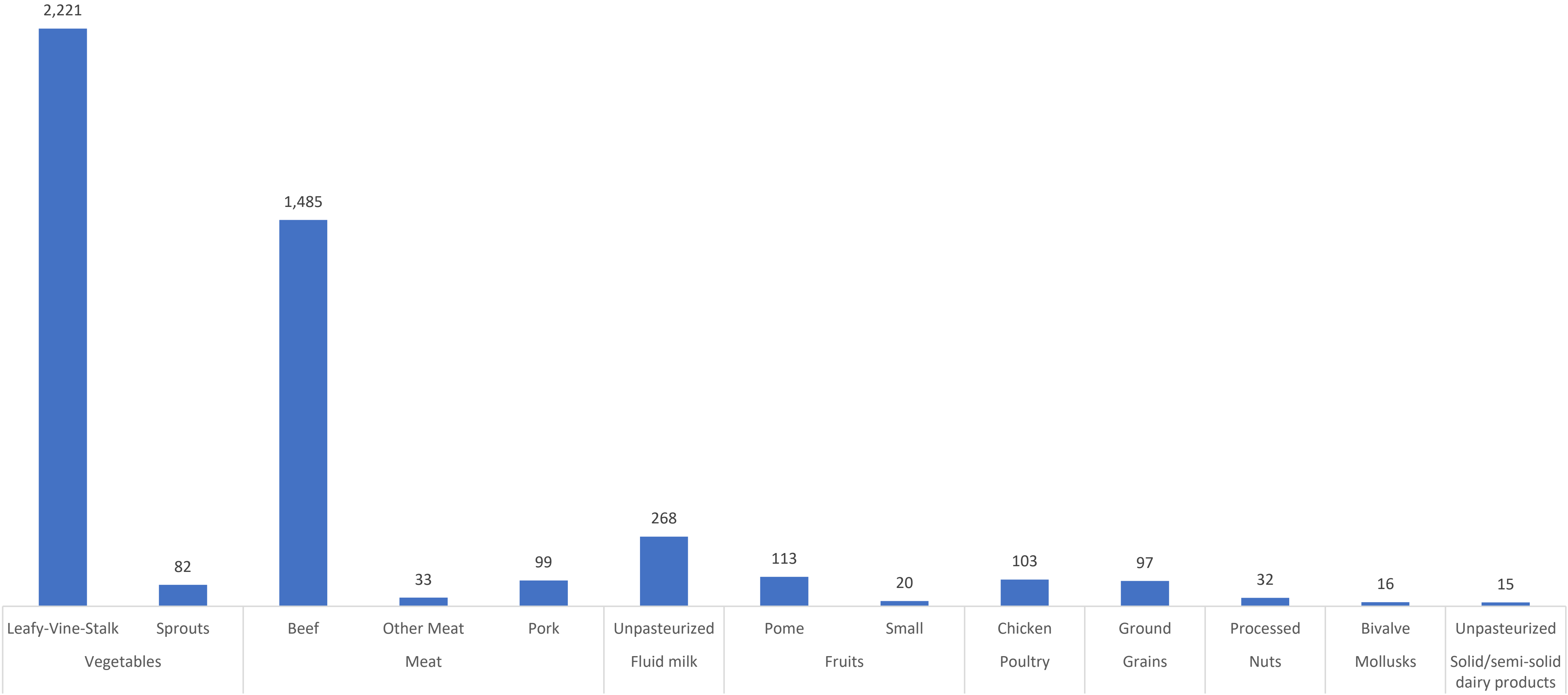


	cantaloupe	chicken, baked	Salad mix, bagged	potato salad	milk, whole milk unpasteurized	pasta salad	turkey, baked	coleslaw	crab salad	Spices	melon
Outbreaks	18	9	3	29	62	19	11	22	5	6	4
Illnesses	996	970	949	931	895	891	866	866	842	807	800

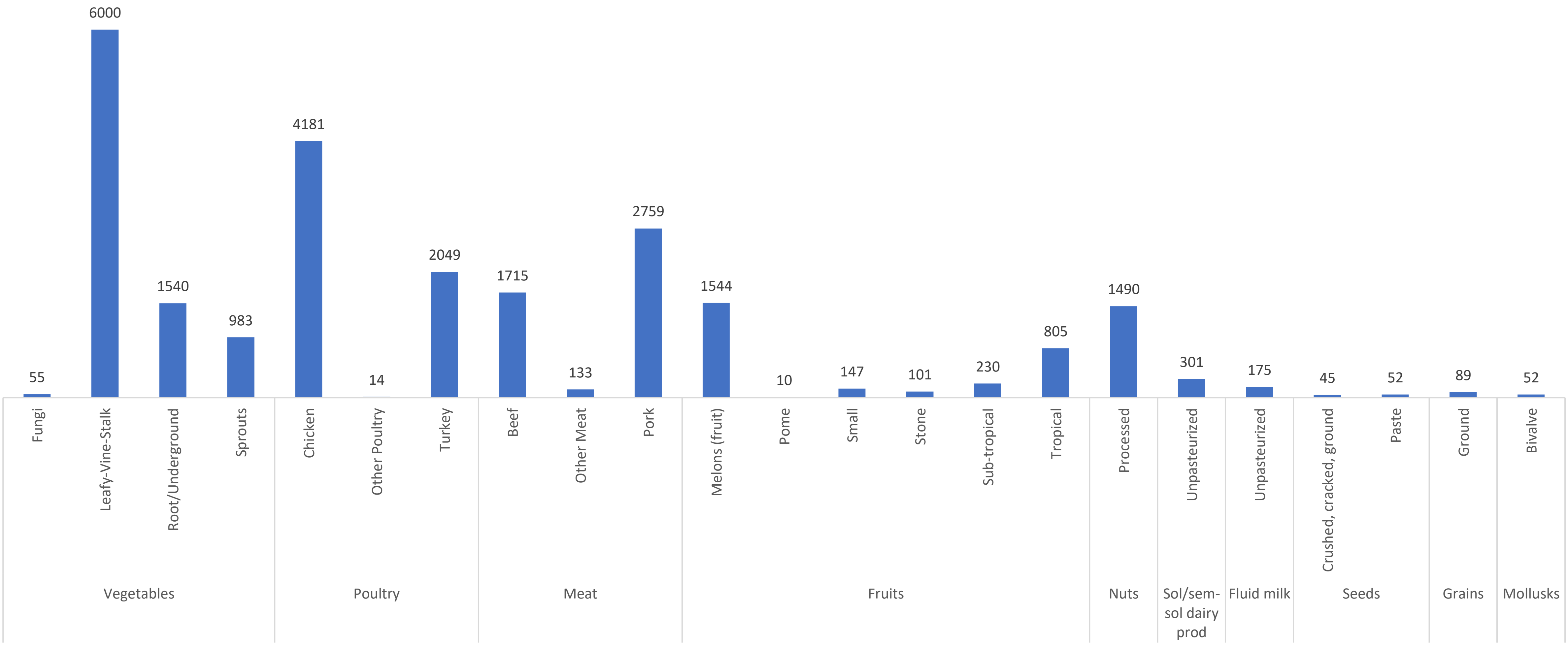
Foodborne Campylobacteriosis Illnesses: Both IFSAC-3 and -4 Data (2005-2020)



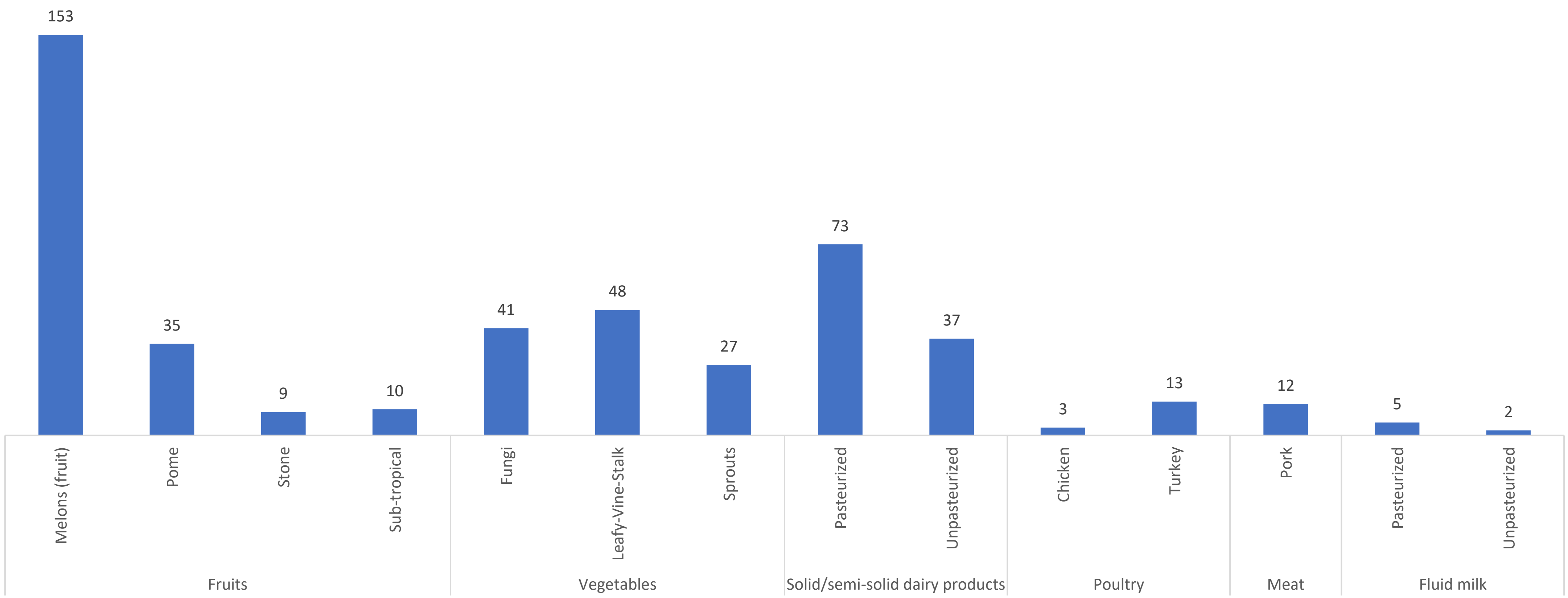
Foodborne Pathogenic *E. coli* Illnesses: Both IFSAC-3 and -4 Data (2005-2020)



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



Foodborne Listeriosis 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)				

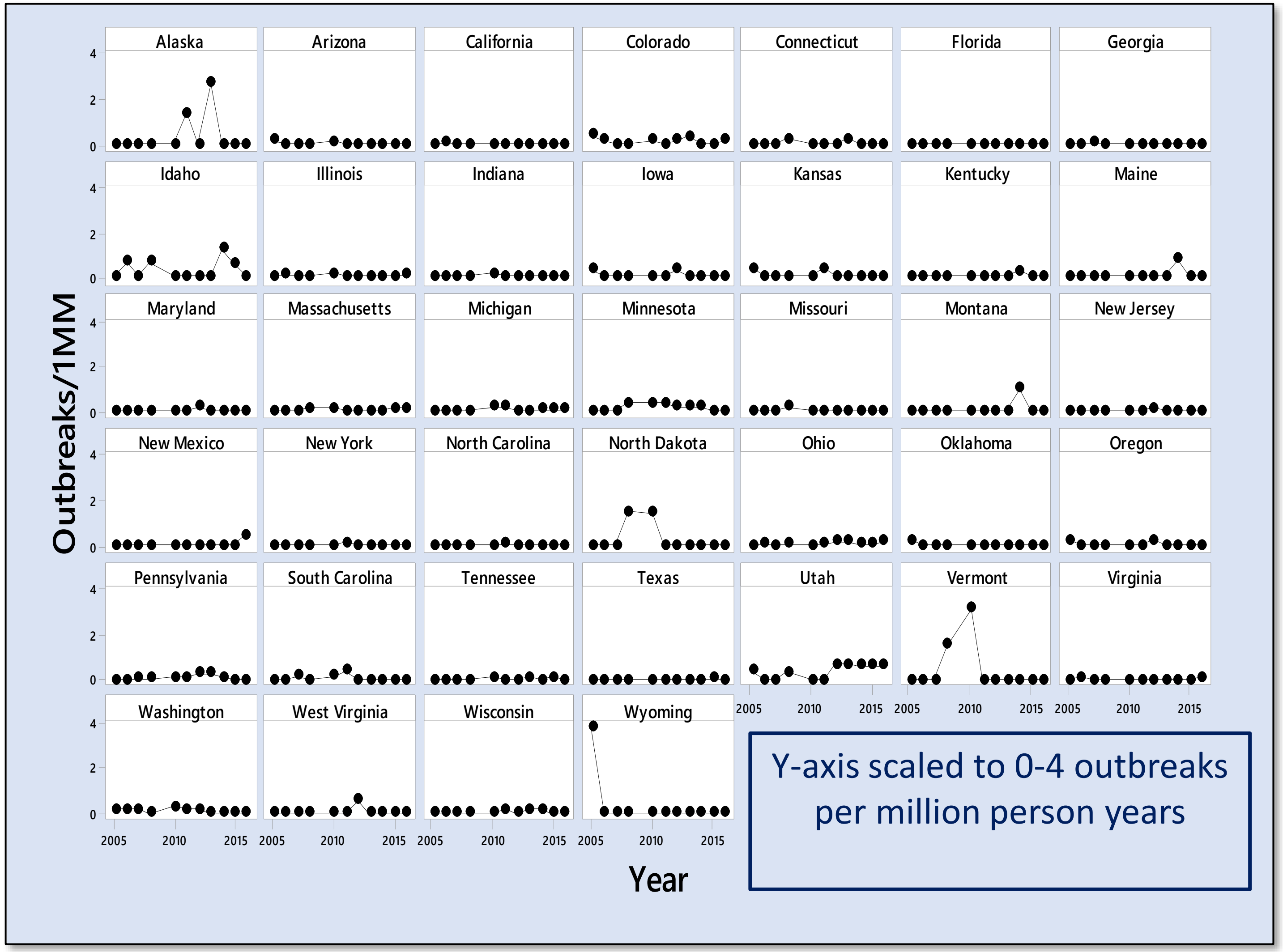
Illnesses by State (2005-2020): Raw Cow/Goat Milk

<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 (2005 – 2016)

Verified by Mann-Kendall Test for Trend



An Evidence Map for Bovine Milk

Product of Ongoing SRA Microbiota of Milks Project

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

Pro Supplemental Studies on Mechanisms

- Murine models, experimental systems for microimmunosomes, indirect colonization resistance
  - Kääriö 2016
  - Melnik 2016
  - Von Mutius 2016
  - Abbring 2017
  - Boudry 2017
  - Mezouar 2018
  - Müller-Rompa 2018
  - Perdijk 2018
  - Abbring 2019
  - Frei 2019
  - Butler 2020
  - Franco-Lopez 2020
  - Hufnagl 2020
  - Quinn 2020
  - Radosavljevic 2020
  - Van Esch 2020
  - Wang 2020
  - Abbring 2021

Contra Supplemental Studies on Mechanisms

- Pathogen susceptibility to innate defenses including microbiota, direct colonization resistance
  - Pricope-Cicolacu 2013
  - McCarthy 2015
  - Buchanan 2017
  - Dietert 2017
  - Schroder 2017
  - Coleman 2018
  - Perdijk 2018
  - Benmoussa & Provost 2019
  - Li 2019
  - Lima 2019
  - Melnik & Schmitz 2019
  - Wu 2019

supporting

- *MA* (**Brick 2020**) and *CSs* (**Loss 2015; Brick 2016; Schroder 2017; Müller-Rompa 2018**) Loss of protection against asthma, allergies, gut, respiratory diseases for children, adults consuming boiled or pasteurized milk; (**Butler 2020**) increased richness gut-brain modules, decreased anxiety (**Wyss 2018**); increased pulmonary function
- **CSs (House 2017; Schröder 2017; Abbring 2019; Sozańska 2019)** Raw milk, raw milk whey proteins, farm/rural environments protect against allergies, asthma, wheezing
- **CS (Wyss 2018)** Higher pulmonary function in raw milk consumers

Pro-Argument on Benefits of Raw Bovine Milk

Extensive evidence from large cohort studies on protective effects

1. Raw versus boiled or pasteurized milk, reducing incidence and severity of infectious diseases of gut and respiratory systems
2. Extensive evidence for protective effects against non-communicable diseases, including asthma, atopy, eczema, wheezing and improved pulmonary, gut, immune system functioning

attenuating

- No studies identified that attribute benefits to specific raw milk microbes or microbial consortia

supporting

- **QMRAs (FDA/FSIS 2003; EFSA 2015; Giacometti 2015a,b, 2017)** Estimate risks for raw milk associated with *Campylobacter*, enteropathogenic *E. coli*, *Listeria monocytogenes*, *Salmonella*
- **Ois (Jaros 2008; Whitehead & Lake, 2018)** Raw milks associated with outbreaks, illnesses, deaths
- **Exp** studies from Canada, Finland, Germany, Poland, US, UK (Table 1)

Contra-Argument on Risks of Infectious Diseases with Raw Bovine Milk

One early systematic review and recent QMRA reassessments and outbreak investigations

attenuating

- **QMRAs (FDA/FSIS 2003;** reassessments **Latorre 2011, Stasiewicz 2014, Buchanan 2017)** and **Rev (EFSA 2015; Berge and Baars 2020)** Limited evidence, pathogen levels, growth in milks, dose-response
- **QMRA (FDA/FSIS 2003) Oi (Whitehead & Lake, 2018) CS (Loss 2015)** Illness, mortality rates for raw milk not higher than pasteurized or boiled milks
- **Ois (Jaros 2008; Whitehead & Lake, 2018; Hanson 2019)** Pasteurized milk associated with outbreaks, illnesses and deaths

Evidence Basis

- **1 MA;** 9 ***CSs*** including 1 experimental ***DBHPP; 7 QMRAs;*** 3 ***Ois*** including 1 ***SR;*** 2 **Rev,** 9 **Exp:** Cite consistent evidence
- 30 supplemental studies on plausible mechanisms for effects

Conclusions

1. Overall biological benefits associated with raw milk consistent across multiple large ***CSs*** and a ***DBHPP***, with supplemental studies on plausible mechanisms
2. Limited evidence for milk-borne risks of infectious diseases in children and adults for both raw and pasteurized milks

Remaining Uncertainties

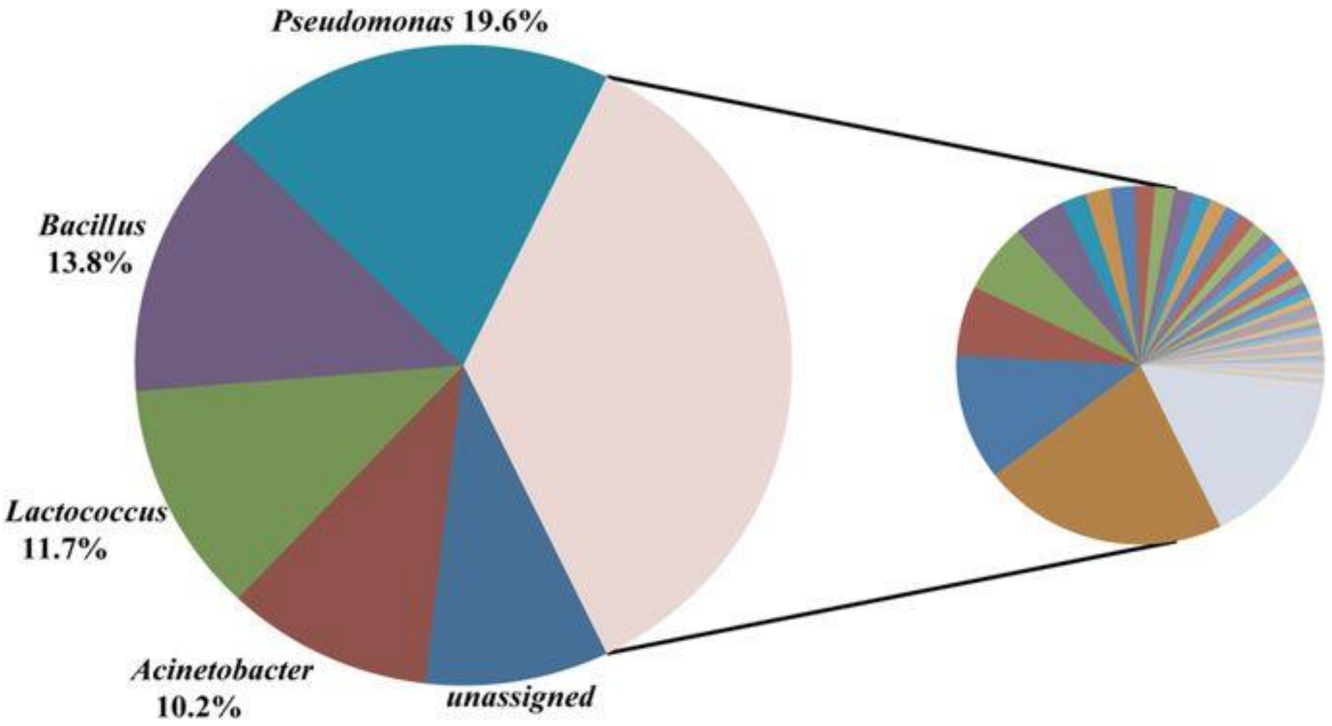
- Are levels of pathogens in raw milk (and milk microbiota) predictive of risks (and benefits)?
- Is risk to children higher than adults based on current evidence and analysis?
- Is 'zero tolerance' for pathogens in raw milk scientifically, economically, ethically defensible?
- Who benefits from access to raw and pasteurized milks?
- What level of risk reductions are achievable for HACCP, cold chain, other?

What Do We Know about "Core" Cow Milk Microbiota?

1. **Predominantly dense rich commensals** that facilitate fermentation, cause spoilage, promote health

2. **Diverse** microbes, 785 genera, 70% less than 1% abundance

3. **Rare detection** of **potential pathogens** (*Campylobacter*, *Listeria*, *Salmonella*), 5 of 112 raw milk samples positive, accounting for <1/10,000 total bacteria



Four Most Prevalent Bacterial Genera
Li et al. 2018

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

Key Questions from a Microbiologist

Q_1: Ideology, Politics, or Science as Tipping Point for Decision Makers?

Q_2: How might openness to analysis and deliberation of recent scientific advances enable future Evidence-Based Risk Management?

Q_3: How might SRA open discourse and provide guidance on quality analysis?

Q_4: How might SRA Acknowledge Evidence of Pro-Pasteurization Bias and Promote Evidence-Based Risk Management?

Q_5: Where have foodborne deaths occurred since 2003 in the US and 2009 in Australia and New Zealand?

Q_6: Are predictions supported by valid data and analysis?

Q_7: Why are NY and other US states monitoring raw milk for Lm, *Salmonella* and STEC when no outbreaks have been reported? (Last campylobacteriosis outbreak 2014)

Q_8: Where is the evidence supporting the ideology that raw milk is an inherently dangerous food?

Q_9: Who cares (or should care) about quality analysis and developing a culture of quality analysis?

Q_{10}: Who will continue the dialogue and contribute to a manuscript?

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.

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

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;

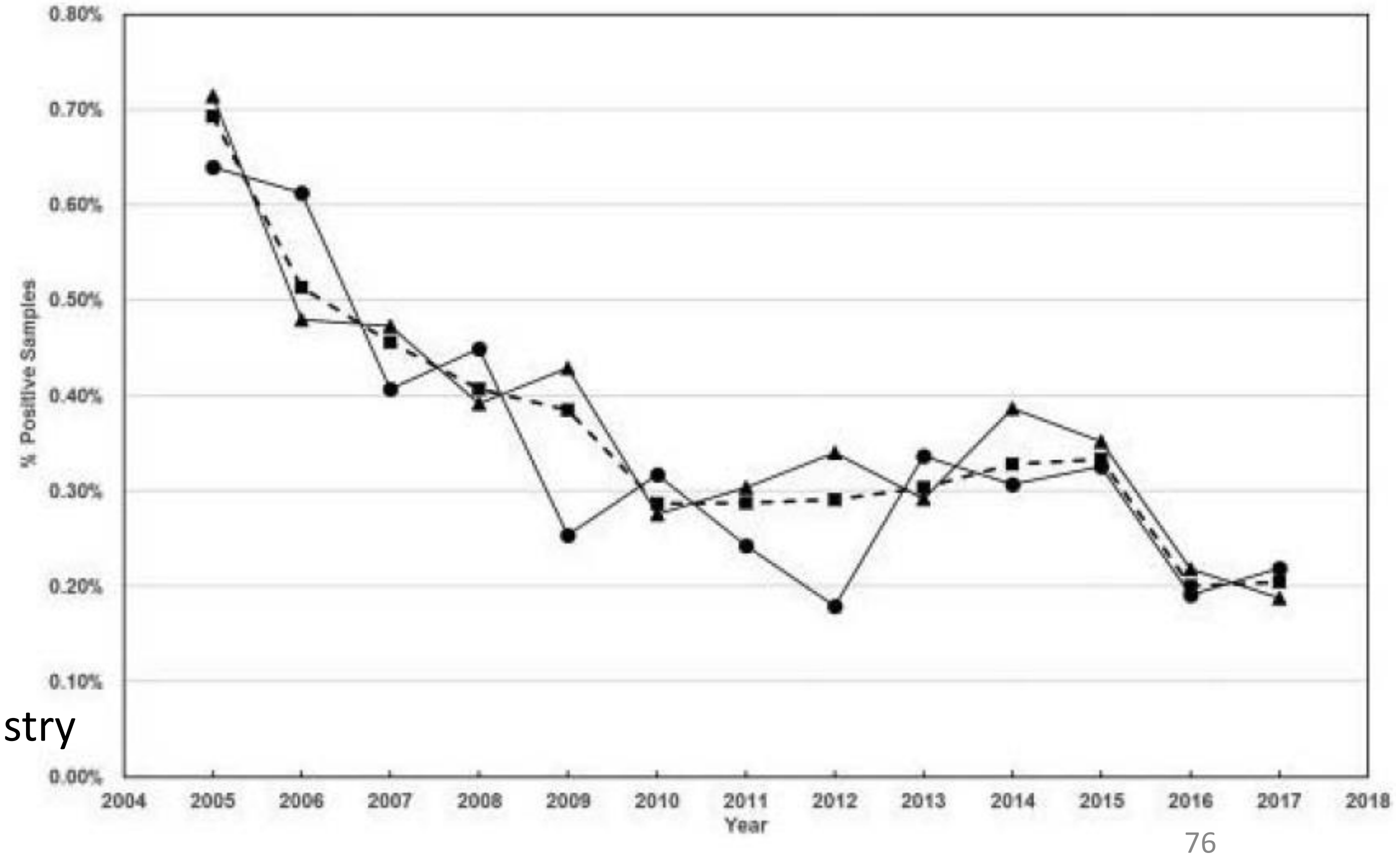
7. Initiate projects with **retail** operations (e.g. delicatessens, salad bars) to pilot new Lm **control measures** including **employee practices**; and

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

FSIS Regulations Contribute to Lm Reductions in RTE Meat/Poultry

(Mamber et al., 2020)

- Percentage Lm positives FSIS RTE:
  - >4.5% in 1990
  - ~0.9% by 2005
  - ~0.2% by 2017
- Regulatory changes
  - Pathogen Reduction and Hazard Analysis and Critical Control Points (HACCP) rule, 1996
  - 9 CFR 430 (the *Listeria* rule) in 2003
    - alternatives 1, 2a, and 2b (postlethality treatments and/or antimicrobial agents and processes)
    - alternative 3 (sanitation only)
  - Intensified verification testing program (follow-up sampling program for products, food contact surfaces, and environmental surfaces Lm-positive establishments)
  - FSIS directives, notices, compliance guides for industry
- Few outbreaks (2005, 2018, total 21 illnesses)



Polling Energy Among Workshop Participants

Deeper Dialogue about RAQT and Quality Analysis

Interested in opportunities to:

1. enhance risk education within and outside SRA membership?

2. provide full disclosure about assumptions and impacts on estimated risks and benefits?

3. promote a broader culture of quality analysis that the contributors to the 2021 RAQT envision?

4. encourage updating and re-assessment for historical and current risk assessments?

5. contribute to workshop manuscript?

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