



# Final Report

## Database of Primary Microbial Testing Program Data for Raw Milk Stored in Microsoft Access®

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Date Submitted: 27 August 2021

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## EXECUTIVE SUMMARY

The Weston A. Price Foundation (WAPF) provided Coleman Scientific Consulting (CSC) primary source data on microbial testing results for raw milk samples collected and analyzed by various states who responded to Freedom of Information Act (FOIA) requests for this project. Qualifications of the consultants are provided in Appendix 1.

The objectives of the project were:

1. Compile microbial testing data for raw milk provided by states under FOIA and other data available from certified laboratories into a Microsoft Access® database;
2. Summarize results for raw cow milk samples collected and analyzed by states under their various licensing programs, including:
  - major foodborne pathogens (*Campylobacter coli/jejuni*; *E. coli* O157:H7 (STECs/EHECs/VTECs); *Listeria monocytogenes*; and *Salmonella* spp.)
  - uncommon foodborne pathogens (*Staphylococcus aureus* and *Yersinia* spp.) and
  - microbial hygiene indicators (standard plate counts (SPCs) or total aerobic plate counts (APCs) and coliforms);
3. Discuss implications of these data for risk assessment.

Four states responded to FOIA requests and provided quantitative data on pathogen occurrence (presence/absence) (CA, NY, TX, WA). These four states also provided data on the levels of microbial indicators of proper hygiene.

Results for pathogens and indicators in raw cow milk from state testing programs (CA, NY, TX, WA) are summarized in the following sub-section and the body of the report. One state (TX) provided data on *Yersinia* spp. and *Staphylococcus* enterotoxin uncommonly associated with raw milk outbreaks. One state (NY) also provided quantitative data on the opportunistic pathogen *S. aureus* that are summarized in Appendix 2. Some microbial standards for milk are listed in tables in the body of the report and in Appendix 3.

Other states that provided only data on microbial indicators (not on pathogens; AZ, ID, MA, NH, SD) were also included in the Microsoft Access® database. Results are summarized in Appendix 4.

Excluded from the database at present are data from the following states (CT, ME, MO, NM, SC, UT, VT) that did not provide microbial results, required payment, or required manual input of data that did not convert successfully from the pdf provided by states in response to the FOIA requests.

In addition to the FOIA data on microbial pathogens and indicators of proper hygiene, data from two certified laboratories were incorporated in the Microsoft Access® database: pathogen testing results for the British Columbia Herdshare Association's 'BC Fresh Milk Project'; and pathogen testing from the 'Test-and-Hold Program' of Organic Pastures, LLC. Results are summarized in Appendix 5.

Data on raw whole cow milk are summarized herein. Data on skim milk, cream, bulk tank milk, raw milk not specified as cow, commingled milk, chocolate milk from cows, and raw goat milk are included in the Microsoft Access® database, but are not summarized herein. No statistical analysis was conducted for this project to date. Tests for significance of potential differences in microbial results within or between states over time may be conducted in the future.



## Summary of Findings

Summaries of results are included below for the four states that provided data on both major pathogens and microbial indicators for raw milk from cows (CA, NY, TX, and WA).

A summary table of results for presence/absence of major microbial pathogens in raw milk samples from culture-based methods provided by four states (CA, NY, TX, and WA) is listed below (Table 1). For these four state sampling programs, the overall totals for percentage of samples with detectable pathogens are 0.5% for *Campylobacter*, 0% for STEC, 0.3% for *Listeria monocytogenes*, and 0.4% for *Salmonella*. Charts by state are included in the body of the report. Noncompliant samples positive for any of the major pathogens trigger regulatory action (recalls and follow-up testing). None of the U.S. states determine the levels of major pathogens in positive raw milk samples.

**Table 1.** Results for Detection of the Presence of Major Microbial Pathogens in Raw Milk from Licensed Dairy Farms in Four State Sampling Plans

| State                 | <i>C. jejuni/coli</i>      | <i>E. coli</i><br>O157:H7/STECs | <i>L. monocytogenes</i>   | <i>Salmonella</i> spp.     |
|-----------------------|----------------------------|---------------------------------|---------------------------|----------------------------|
| CA                    | 0/61                       | 0/61                            | 0/61                      | 0/61                       |
| NY                    | 6/783<br>(1.3%)            | 0/782                           | 1/781<br>(0.1%)           | 0/780                      |
| TX                    | 4/601<br>(0.7%)            | 0/596                           | 4/596<br>(0.7%)           | 11/606<br>(1.8%)           |
| WA                    | 0/497                      | 0/502                           | 0/502                     | 0/494                      |
| <b>Overall Totals</b> | <b>10/1,942<br/>(0.5%)</b> | <b>0/1,941</b>                  | <b>5/1,940<br/>(0.3%)</b> | <b>11/1,941<br/>(0.4%)</b> |

A summary table of results for quantitative data (counts or colony forming units (cfu) per mL) on microbial hygiene indicators in raw milk samples is listed below (Table 2). Percentage compliance with state standards for coliforms and SPCs, respectively, were 80% and 96% for CA, 70% and 89% for TX, and 84% and 89% for WA. Compliance with NY state standards for SPCs were 93% for NY (coliform testing not routinely conducted). Charts by state are included in the body of the report.

**Table 2.** Results for Compliance of Levels of Microbial Indicators with Microbial Standards for Raw Milk from Licensed Dairy Farms in State Sampling Plans

| State | Coliform Compliance<br>(# samples <10/mL/total #<br>samples, percentage<br>compliant) | SPC Compliance<br>(# samples <standard/total #<br>samples, percentage compliant) | State SPC Standards<br>(cfu/mL) |
|-------|---|--|---------------------------------|
| CA    | 123/154 (80%)   | 199/207 (96%)  | 15,000                          |
| NY    | Not Tested  | 1,382/1,459 (93%)  | 30,000                          |
| TX    | 1,392/1,986 (70%)   | 1,614/1,809 (89%)  | 20,000                          |
| WA    | 472/562 (84%)   | 502/564 (89%)  | 20,000                          |



## Application of Findings to Microbial Risk Assessment

Many data gaps significantly limit confidence in simulation results on possible risks associated with raw milk, including data gaps for Exposure Assessment that the data in the Microsoft Access® database address, as described in more detail herein.

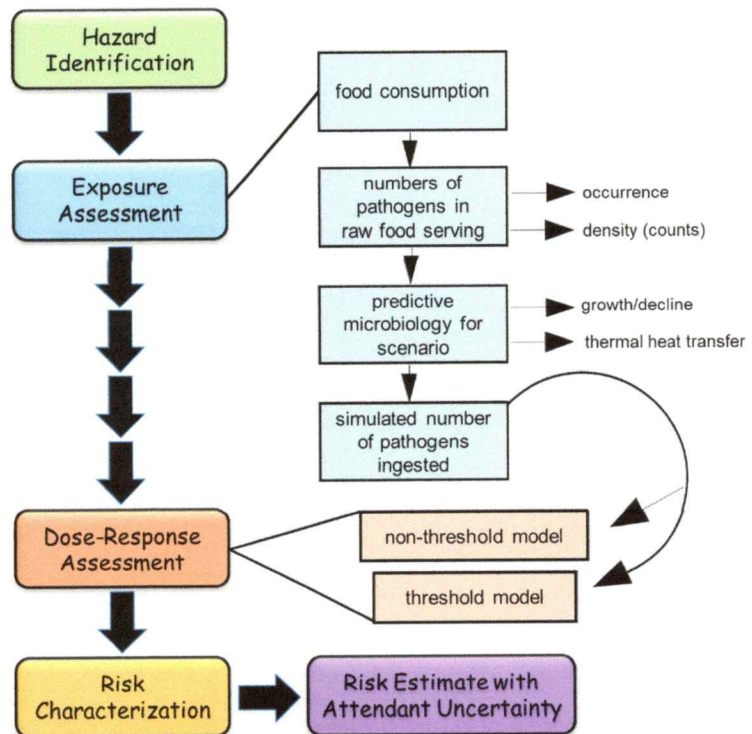
The Quantitative Microbial Risk Assessments (QMRAs) conducted for foodborne pathogens in raw milk by governmental teams in the US (FDA/FSIS, 2003) and Australia and New Zealand (FSANZ, 2009), as well as a recent review conducted by the European Food Safety Authority for raw milk QMRAs (EFSA, 2015), acknowledge significant data gaps for the elements of risk assessment relevant to raw milk:

- Hazard Identification;
- Exposure Assessment;
- Dose-Response Assessment; and
- Risk Characterization.

Note that the common assumption in the pro-pasteurization literature and court, decisions, that risk is estimated from outbreaks, is grossly erroneous, as explained in the body of the report. Proponents of this assumption often appear to ignore decades of analysis developing and improving methods for QMRA so that assessments might become ‘soundly based on science’ and include estimates of uncertainties as laid out by international consensus and in the peer reviewed literature (CAC, 1999; Coleman et al., 2018).

One aspect noted in the 1999 consensus document on principles and guidelines for microbial or microbiological risk (CAC, 1999) is the need for re-assessment when additional data become available. Re-assessment is particularly important when the currently available data conflict with the assumptions or data applied in the initial microbial risk assessment conducted in the past. Such is the case with both government QMRAs cited herein.

The available evidence included in the Microsoft Access® database and other published and unpublished data falsify the assumption that raw milk is inherently dangerous and a major public health hazard. This database provides source data to inform future QMRAs and benefit-risk assessments.



**Figure ES-1.** Elements of Microbial Risk Assessment (Modified from Figure 1 in Marks et al., 1998) incorporating Trans-Disciplinary Research for Assessing Risk with Attendant Uncertainty. The primary disciplines informing each element include: epidemiology for Hazard Identification; microbiology for Exposure Assessment; medical microbiology for Dose-Response Assessment; and statistics for scenario modeling for Risk Characterization.

## DATA AND METHODS

The primary data source for this project was microbiological test results from state sampling plans for dairies licensed to sell raw milk in the US. The data were provided in response to FOIA requests by Mr. Daniel Andras (Andras, 2021). Qualifications of the consultants for this project are summarized in Appendix 1.

The microbial data provided by states was screened for format and ease of input into a Microsoft Access® database. Quantitative microbial data included direct plate-counting methods (colony forming units or cfu/mL) or indirect estimation methods (statistical likelihood of counts/mL as Most Probable Number (MPN/mL) from dilution series for microbial hygiene indicators and the opportunistic pathogen *S. aureus*. Some states also provided qualitative microbial data (presence/absence) for major foodborne pathogens. Also included in the Microsoft Access® database but not summarized herein is data on the host (cow, goat, or sheep) milk quality indicator associated with animal health, somatic cell count (SCC).

The following table summarizes the data provided by states in response to the FOIA requests.

**Table 3.** Format and Extent of Data Provided by States in Response to FOIA Requests

| State | # Original Files | PDF | Excel | Converted | #Worksheets |
|-------|------------------|-----|-------|-----------|-------------|
| AZ    | 7                | 1   | 6     |           | 6           |
| CA    | 2                | 2   | 1     | yes       | 20          |
| CT    | 1                |     |       |           |             |
| ID    | 1                | 1   | 1     | yes       | 24          |
| MA    | 1                |     | 1     |           | 1           |
| ME    | 1                | 1   | 1     | yes       | 379         |
| MO    | 2                | 2   |       |           |             |
| NH    | 73               |     | 73    |           |             |
| NM    |                  |     |       |           |             |
| NY    | 3                | 2   | 1     | no        | 1           |
| OR    |                  | 2   | 1     | yes       | 4           |
| SC    | 5                | 4   |       |           |             |
| SD    | 2                |     |       |           |             |
| TX    | 2                | 1   |       |           | 1           |
| UT    | 2                | 2   | 1     | yes       |             |
| VT    | 16               | 16  |       |           |             |
| WA    | 41               |     | 41    |           |             |

Data for microbial hygiene indicators and specific pathogens is summarized in charts listed in the next section of this report for four states (CA, NY, TX, WA). One state (NY) also provided quantitative microbial data for the opportunistic pathogen *S. aureus* that rarely causes foodborne disease in the US. A chart summarizing CFU/mL for *S. aureus* is provided in Appendix 2.

Data from other states that provided only data on microbial indicators (not on pathogens; AZ, ID, MA, NH, SD) were also included in the Microsoft Access® database. These data are summarized briefly in Appendix 4.

120 Excluded from the Microsoft Access® database at present are data from the following states (CT, ME,  
121 MO, NM, SC, UT, VT) that did not provide microbial results for raw milk from cows, required payment,  
122 or required manual input of data that did not convert successfully from the pdf provided by states in  
123 response to the FOIA requests.

124 Some clean-up of the data was necessary due to the lack of standardization of reporting within and  
125 between states. Structured queries were performed and saved in the Microsoft Access® database, and  
126 results were exported to Microsoft Excel® workbooks for preparation of charts summarizing the data by  
127 state. No statistical analysis was conducted for this project to date.



## SUMMARY OF MICROBIAL TESTING RESULTS

Summaries of results are included for the four states that provided both microbial indicator and specific pathogen data for raw milk from cows (CA, NY, TX, and WA). A summary table of results for presence/absence of microbial pathogens in raw milk samples provided by these four states is listed below (Table 1). For these four state sampling programs, the overall totals for percentage of samples with detectable pathogens are 0.5% for *Campylobacter*, 0% for STEC, 0.3% for *Listeria monocytogenes*, and 0.4% for *Salmonella*.

**Table 1.** Results for Detection of the Presence of Major Microbial Pathogens in Raw Milk from Licensed Dairy Farms in Four State Sampling Plans

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| TX                    | 4/601<br>(0.7%)            | 0/596                           | 4/596<br>(0.7%)           | 11/606<br>(1.8%)           |
| WA                    | 0/497                      | 0/502 O157<br>2/502 non-O157    | 0/502                     | 0/494                      |
| <b>Overall Totals</b> | <b>10/1,942<br/>(0.5%)</b> | <b>0/1,941</b>                  | <b>5/1,940<br/>(0.3%)</b> | <b>11/1,941<br/>(0.4%)</b> |

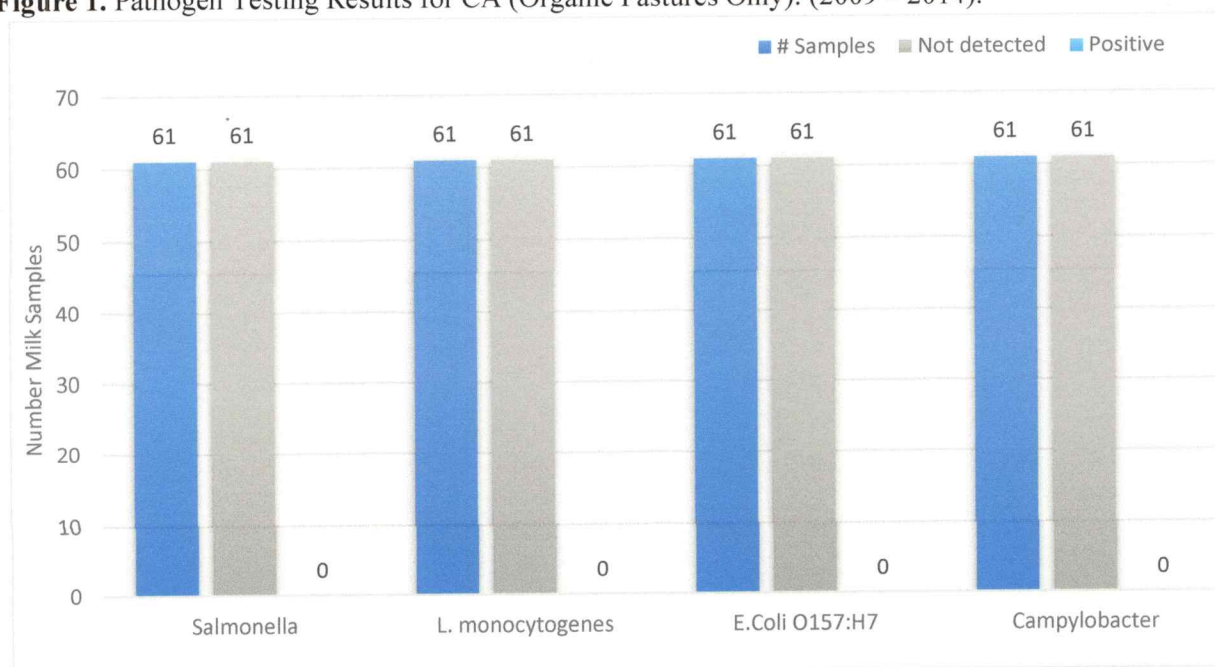
A summary table of results for quantitative data (cfu per mL) on microbial hygiene indicators in raw milk samples is listed below (Table 2). Percentage compliance with state standards for coliforms and SPCs, respectively, were 80% and 96% for CA, 70% and 89% for TX, and 84% and 89% for WA. Compliance with NY state standards for SPCs were 93% for NY (coliform testing not routinely conducted). Charts by state are included in the body of the report.

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| State | Coliform Compliance<br>(# samples <10/mL/total #<br>samples, percentage<br>compliant) | SPC Compliance<br>(# samples <standard/total #<br>samples, percentage compliant) | State SPC Standards<br>(cfu/mL) |
|-------|---|--|---------------------------------|
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| TX    | 1,392/1,986<br>(70%)  | 1,614/1,809<br>(89%)   | 20,000                          |
| WA    | 472/562<br>(84%)  | 502/564<br>(89%)   | 20,000                          |

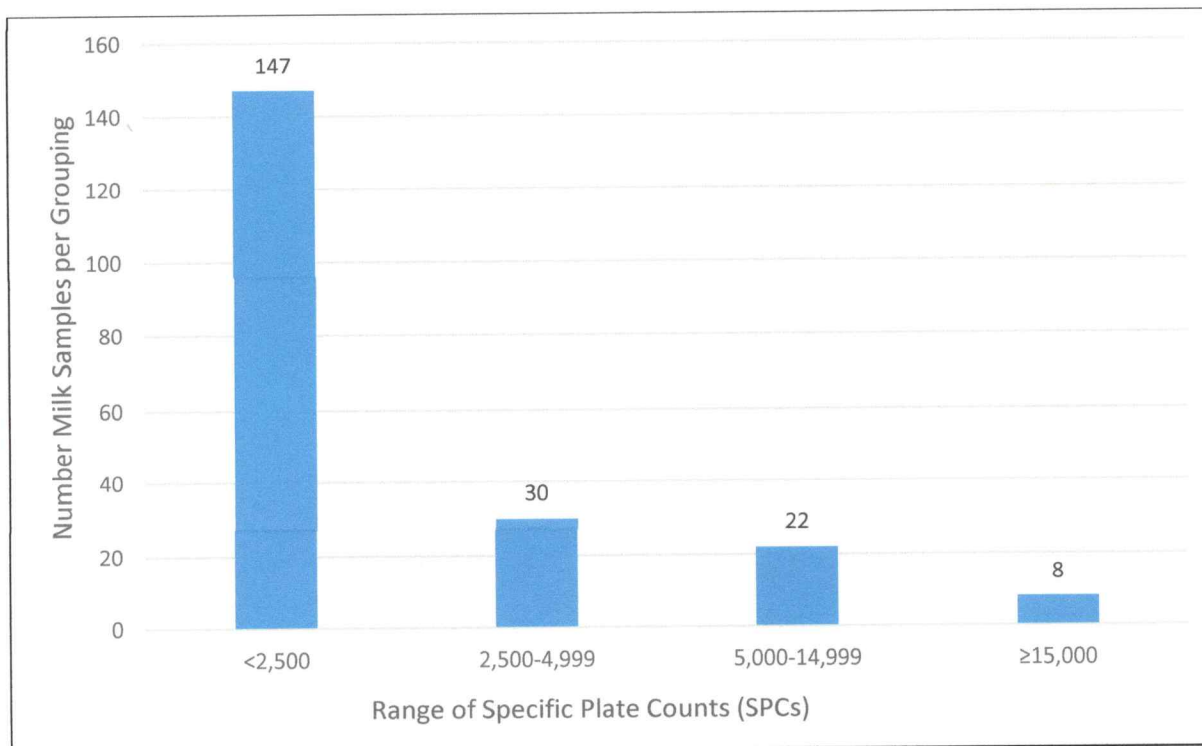
144 Charts summarizing microbial testing results for raw cow milk from CA, NY, TX, and WA are presented  
145 below.

146 **Figure 1.** Pathogen Testing Results for CA (Organic Pastures Only): (2009 – 2014).



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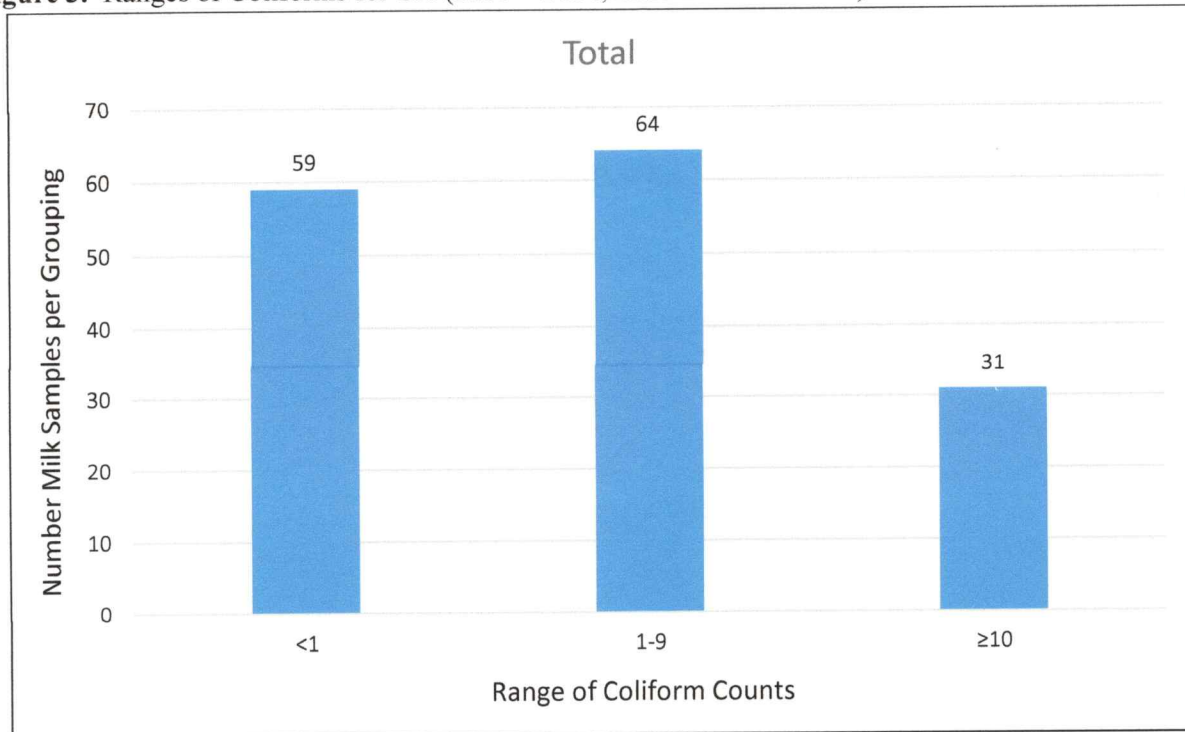
148 **Figure 2.** Range of SPCs for CA (2009 – 2014; maximum value >250,000)



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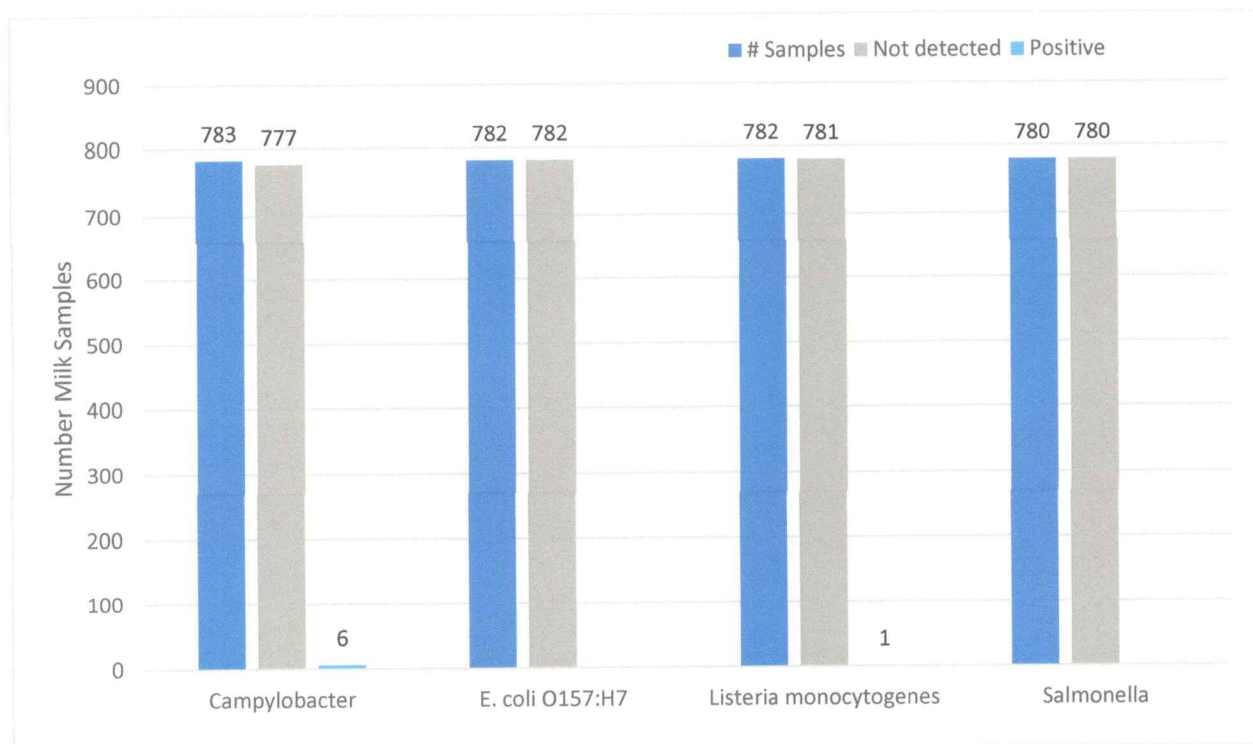
**Figure 3.** Ranges of Coliforms for CA (2009 – 2014; maximum value 410)



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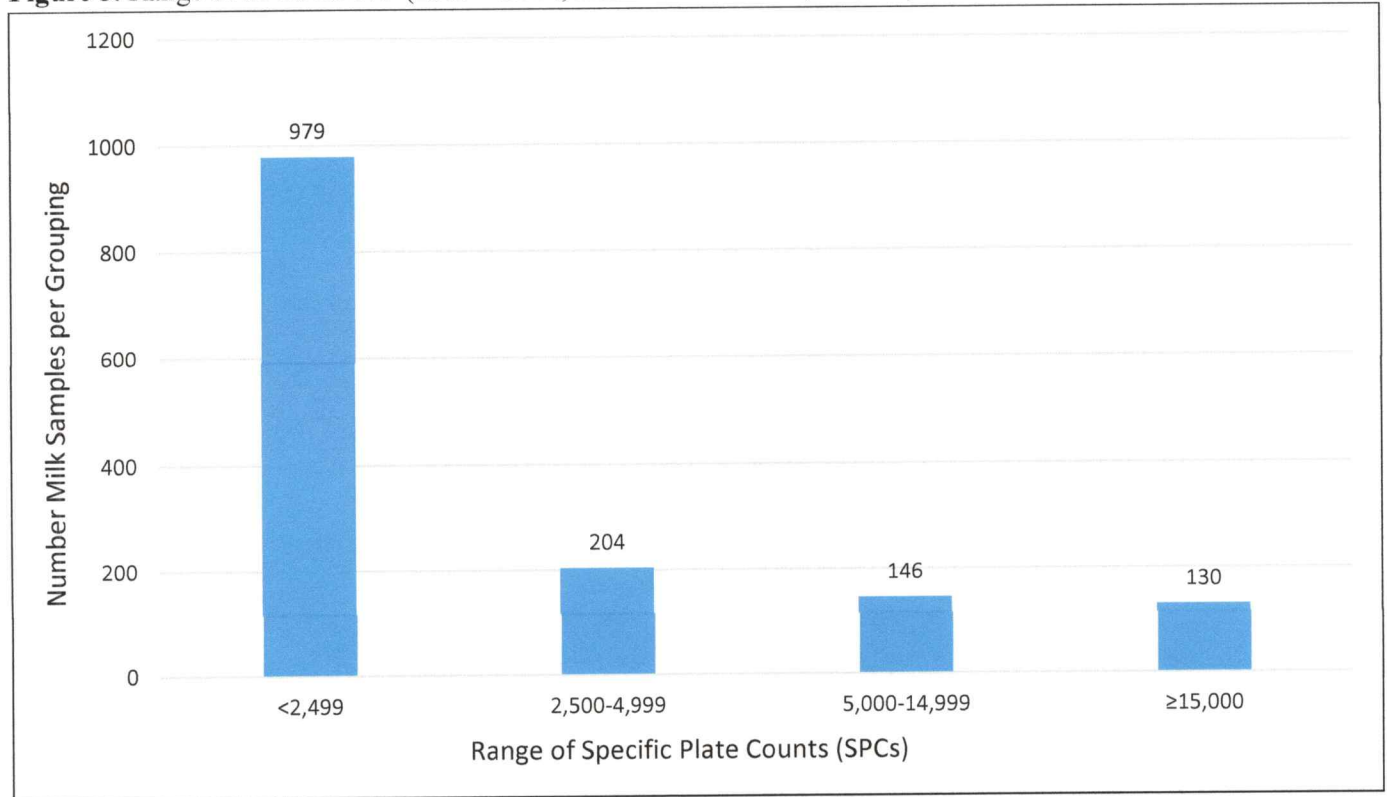
**Figure 4.** Pathogen Testing Results for NY (2009 – 2014)



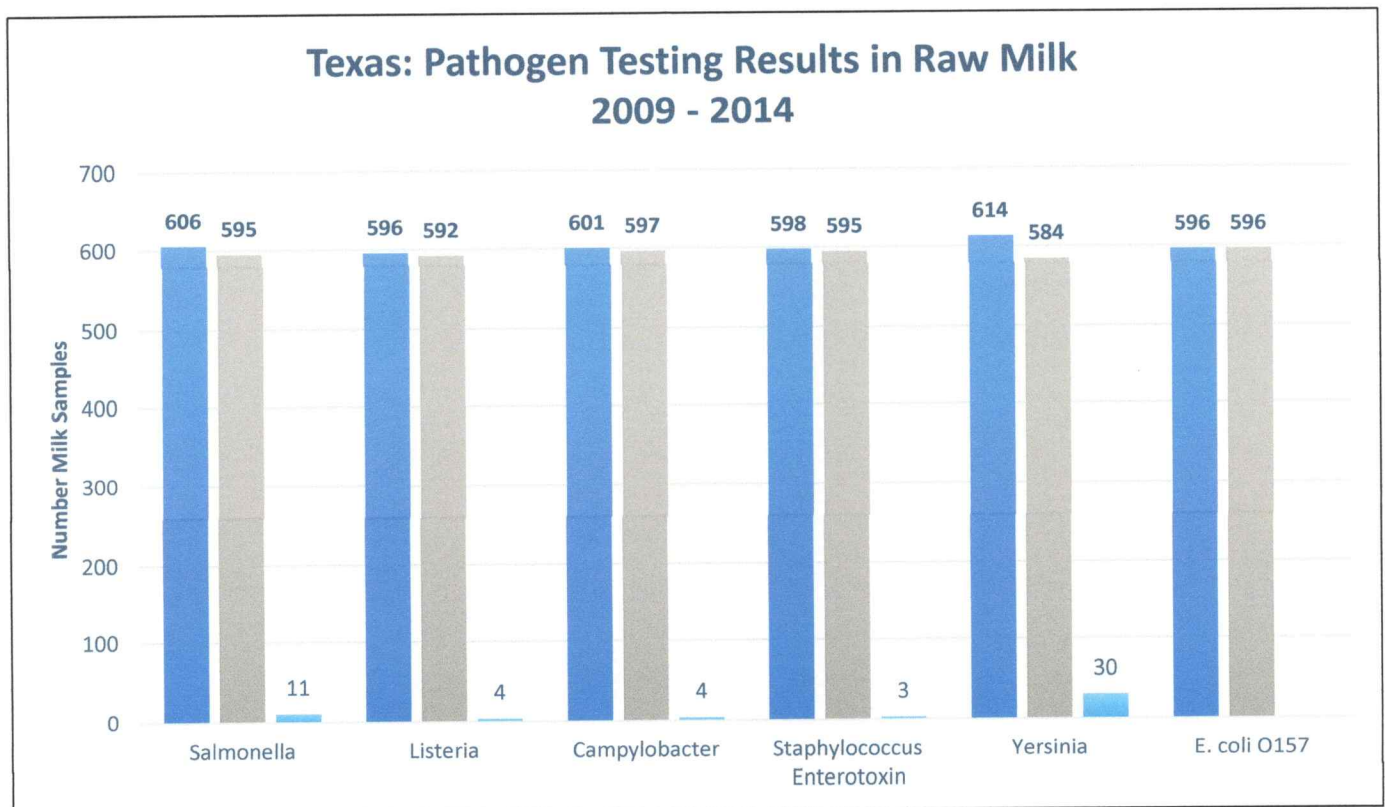
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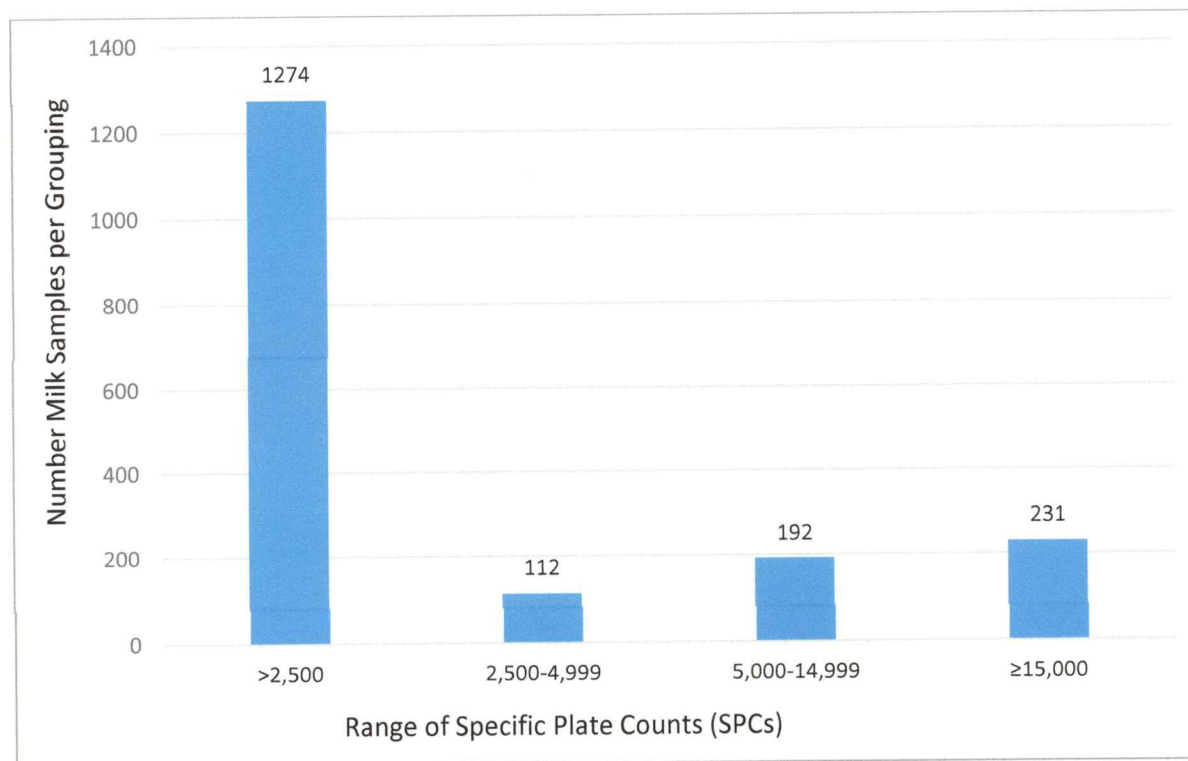
**Figure 5.** Range of SPCs for NY (2009 – 2014; maximum value >6,000,000)



**Figure 6.** Pathogen Testing Results for TX (2009 – 2014)



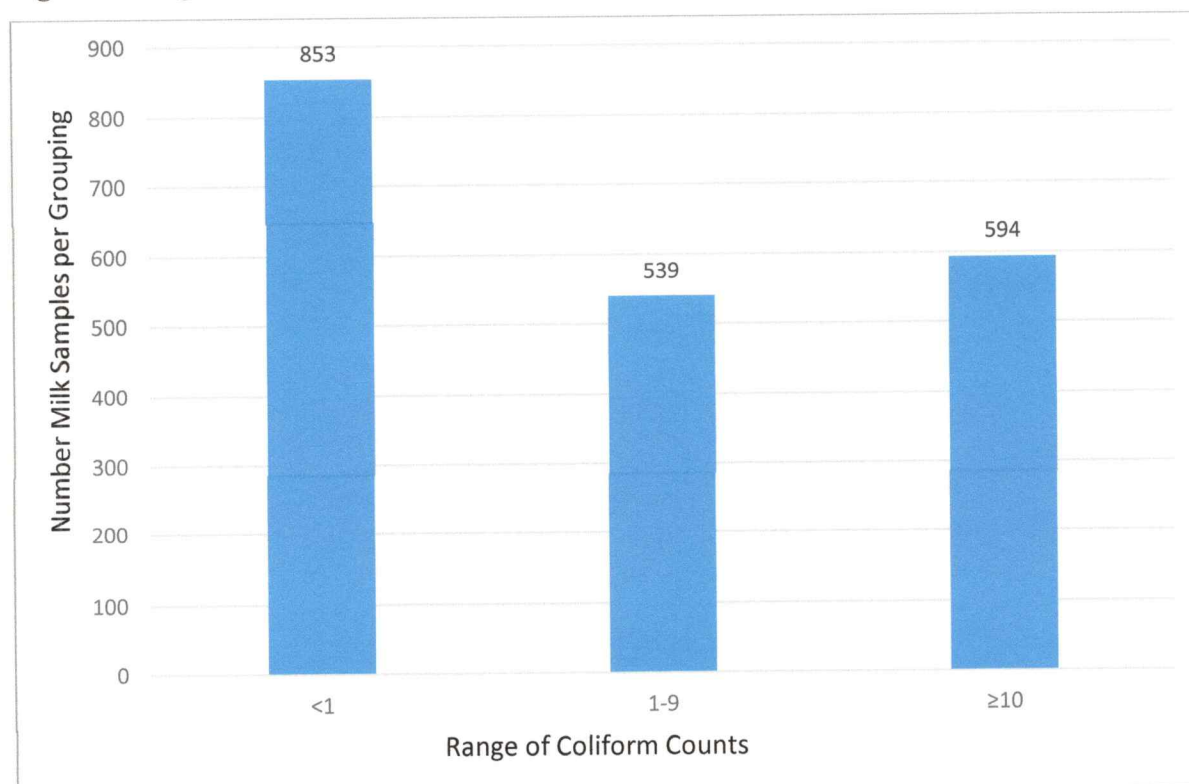
**Figure 7. Range of SPCs for TX (2009 – 2014; maximum value 5,700,000)**



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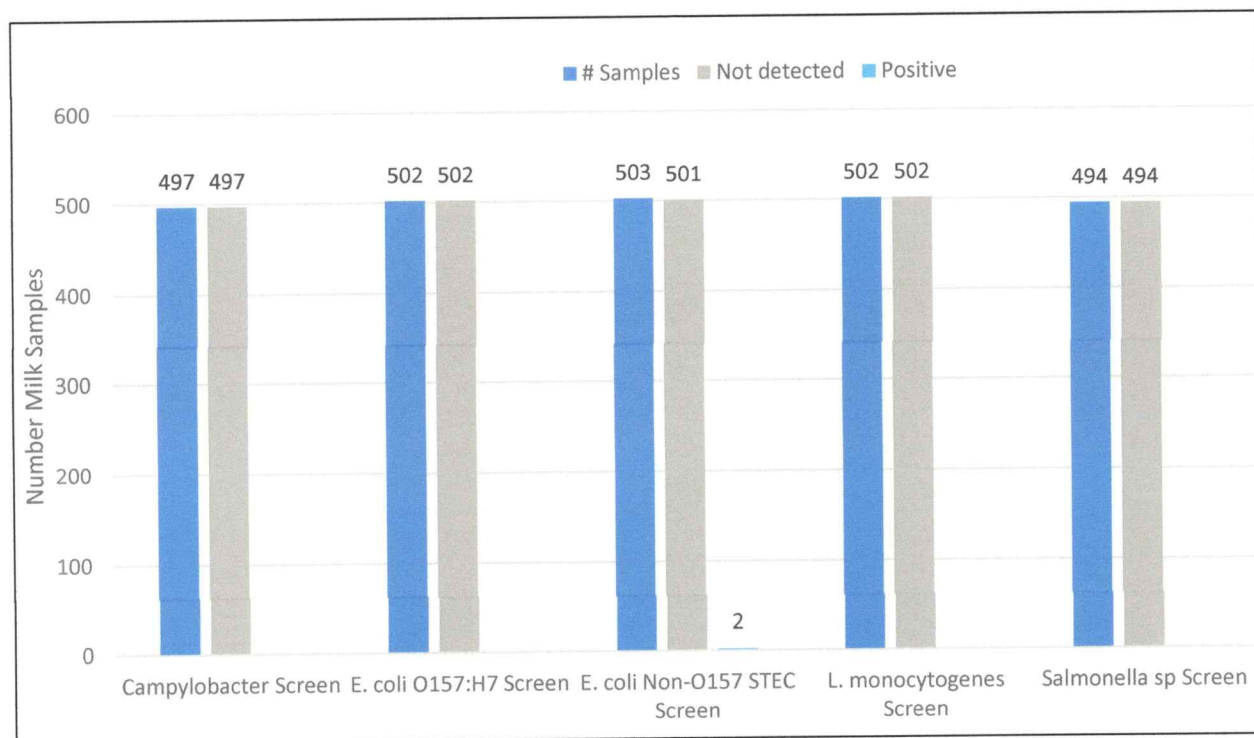
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**Figure 8. Ranges of Coliforms for TX (2009 – 2014; maximum value 2,700)**

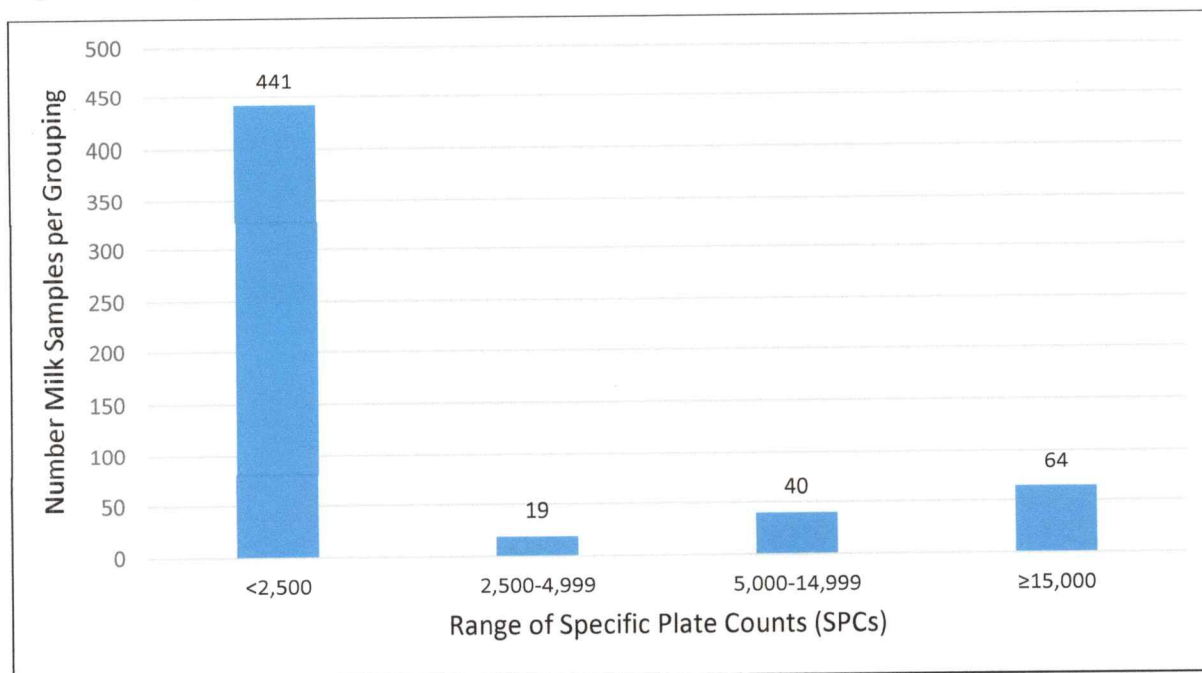


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**Figure 9. Pathogen Testing Results for WA (2012 – 2015)**

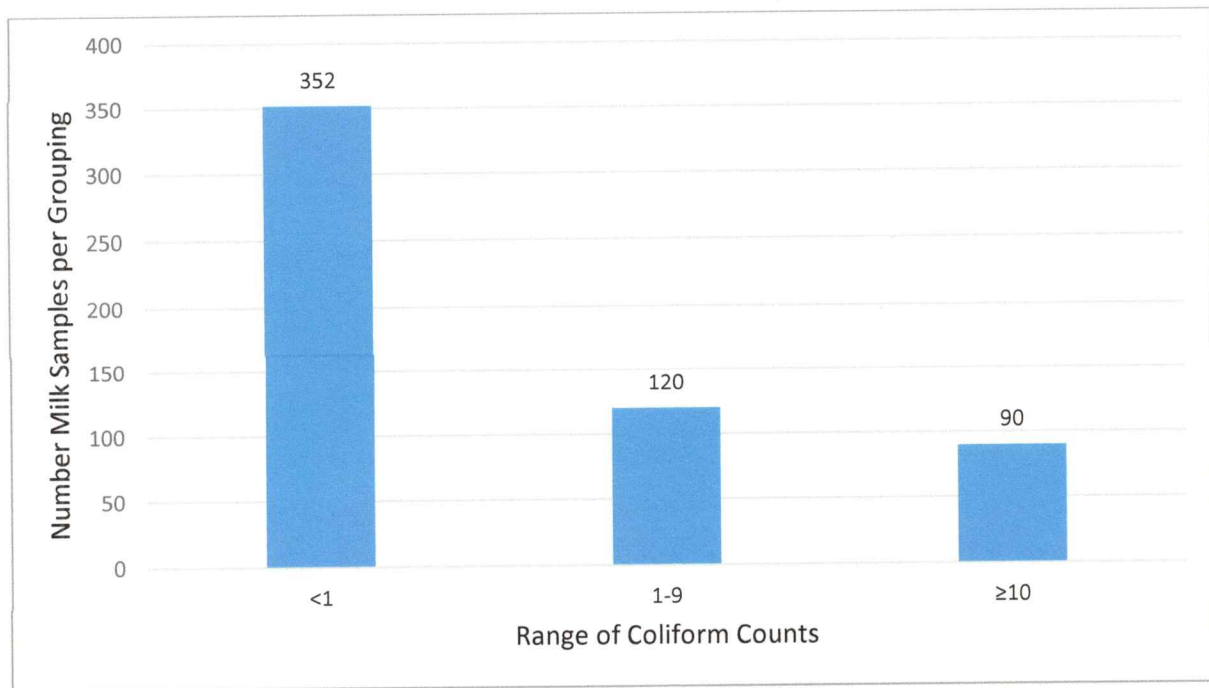


**Figure 10. Range of SPCs for WA (2012 – 2015; maximum value >200,000)**





171 **Figure 11.** Range of Coliforms for WA (2012 – 2015; maximum value >150)



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## DISCUSSION

### Microbial Data and its Interpretation for Risk Assessment

Many data gaps significantly limit confidence in simulation results on possible risks associated with raw milk, including data gaps for Exposure Assessment that the data in the Microsoft Access® database address, as described in more detail herein.

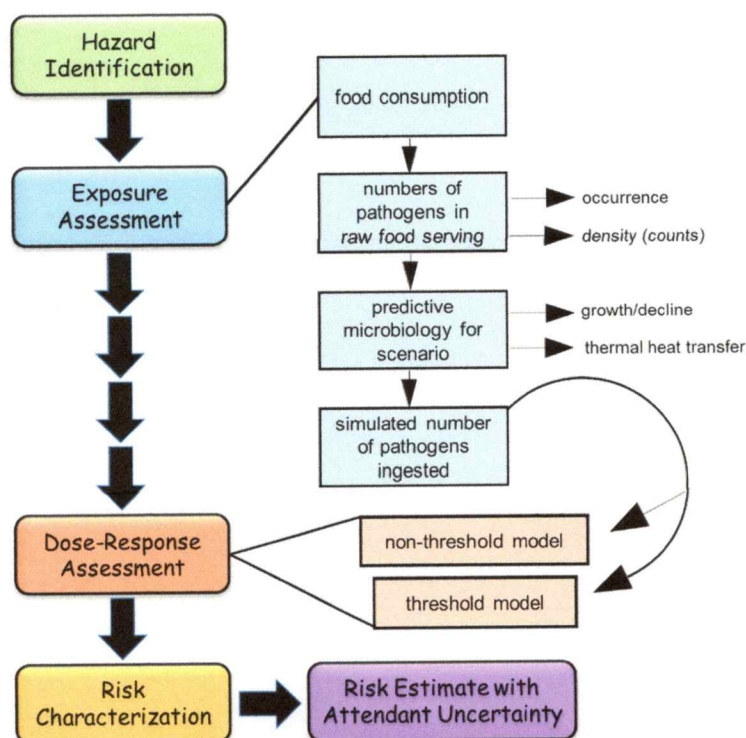
The Quantitative Microbial Risk Assessments (QMRAs) conducted for foodborne pathogens in raw milk by governmental teams in the US (FDA/FSIS, 2003) and Australia and New Zealand (FSANZ, 2009), as well as a recent review conducted by the European Food Safety Authority for raw milk QMRAs (EFSA, 2015), acknowledge significant data gaps for the elements of risk assessment:

- Hazard Identification;
- Exposure Assessment;
- Dose-Response Assessment; and
- Risk Characterization.

Note that the common assumption in the pro-pasteurization literature and court decisions, that risk is estimated from outbreaks, is grossly erroneous. Epidemiologic studies do not estimate risk with attendant uncertainties as described in Figure ES-1. Proponents of this assumption often appear to ignore decades of analysis developing and improving methods for QMRA so that assessments might become 'soundly based on science' and include estimates of uncertainties as laid out by international consensus and in the peer reviewed literature (CAC, 1999; Coleman et al., 2018). Epidemiology is merely one of many scientific disciplines that contribute to microbial risk assessment.

One aspect noted in the international consensus document on principles and guidelines for microbial or microbiological risk (CAC, 1999) is the need for re-assessment when additional data become available. Re-assessment is particularly important when the currently available data conflict with the assumptions or data applied in the initial microbial risk assessment. Such is the case with both government QMRAs cited herein.

Methodology for QMRA has been evolving since the 1990s (Marks et al., 1998; Powell et al., 2000). Principles and guidelines for QMRA were also developed and endorsed with broad international consensus in this period (CAC, 1999). A common misunderstanding of the strongly trans-disciplinary



**Figure ES-1.** Elements of Microbial Risk Assessment (Modified from Figure 1 in Marks et al., 1998) incorporating Trans-Disciplinary Research for Assessing Risk with Attendant Uncertainty. The primary disciplines informing each element include: epidemiology for Hazard Identification; microbiology for Exposure Assessment; medical microbiology for Dose-Response Assessment; and statistics for scenario modeling for Risk Characterization.



nature of risk analysis is that risk is assessed primarily or solely from epidemiologic evidence of outbreaks. A valid QMRA estimates the likelihood or chance of illness (e.g., risk of 1 illness in a million servings, or risk of 1,000 illness per year for consumers), severity, and uncertainty about the likelihood and magnitude of the risk. QMRA is strongly trans-disciplinary, not merely based on epidemiology. Data from all four elements must be included in QMRA, as well as documentation and analysis indicating the coherence, consistency, and rigor of the scientific evidence (e.g., evaluating the ‘state of the science’ for each element) and transparent analysis (e.g., providing code or methodologic details enabling a trained analyst to verify the results). Transparency is also ensured when access to the source data and models are provided, including methods used to model the complex relationships between pathogens, indigenous microbes in the food and the gut, and host cells in the gut and immune systems driving health and disease. Some additional detail is provided for each of the four QMRA elements below.

- Hazard Identification is based primarily on epidemiologic associations for outbreaks (Jaros et al., 2008) and sporadic disease, as well as on clinical data from challenge studies in humans, animals, and *in vitro* model systems including human cell and organ cultures.
- Exposure Assessment is based primarily on data depicting the microbiology and microbial ecology of foods (frequency of positives, levels of positives, growth and survival of pathogens, effects of food microbiota; Coleman et al., 2003a,b; FSNS, 2021).
- Dose-Response Assessment is based primarily on human or animal data from challenge studies at known doses of pathogens. Past models of dose-response relationships are clearly over-simplistic and ignore or exclude evidence on the biological complexity of ‘human superorganisms’ (Dietert, 2016; Coleman et al., 2018; Coleman et al., 2021). Ideally, data are identified in the peer-reviewed literature or generated for the QMRA project to distinguish how known pathogen doses affect the likelihood and severity of illness for both immunocompetent and immunocompromised populations.
- Risk Characterization is based on data and models from the Exposure Assessment and Dose-Response Assessment elements, as well as data for selected scenarios for estimating baseline risk and effectiveness of interventions to reduce risk. For example, data on the effectiveness of Hazard Analysis Critical Control Point (HACCP) programs (Whitehead and Lake, 2018; Berge and Baars, 2020) and Test-and-Hold Programs to reduce risk would be relevant to Risk Characterization. Further, the U.S. National Research Council (NRC, 1996) highlights the critical role communicating the evidence, the ‘state of the science’, uncertainties, and the implications of assumptions and models openly and transparently with all stakeholders of decisions, especially for decision making about controversial societal issues.

Two early QMRAs estimated risks for raw milk consumers in the US (FDA/FSIS, 2003) and Australia and New Zealand (FSANZ, 2009). These QMRA are discussed in more detail in the report prepared for the Australian Raw Milk Movement (Coleman, 2021). Updated re-assessments of the former QMRA by independent academic researchers depicted very low risk for consumers of raw cow milk in the US and higher risk for pasteurized milks processed with increasing temperatures (Latorre et al., 2011; Stasiewicz et al., 2014). No re-assessment of the FSANZ report (2009) has been undertaken to date. An independent critique of the FSANZ report (2009) documents many invalid assumptions and biases that exaggerated risks and underestimated uncertainties (Coleman, 2021).



## Highlights of EFSA Reviews

A subsequent review and analysis of QMRAs for raw milk by the European Food Safety Authority (EFSA, 2015, pg. 4) provided the following perspective for listeriosis in monitoring programs for raw milk.

‘Although *L. monocytogenes* is not considered to be one of the main hazards associated with RDM [raw drinking milk] in the EU, the reviewed QMRAs from outside the EU do show that the risk associated with *L. monocytogenes* in raw cow’s milk can be mitigated and reduced significantly if the cold chain is well controlled, the shelf-life of raw milk is limited to a few days and there is consumer compliance with these measures/controls.’

The statement above from EFSA is also true for the remaining major pathogens (*Campylobacter* spp., EHECs, and *Salmonella* spp.) that cannot outcompete the natural microbiota at refrigeration temperatures (Coleman et al., 2003a). Although the 2003 manuscript reported simulations of potential pathogen growth for risk assessment in ground beef, the data available at the time for all four pathogens, growth of pure cultures in rich nutrient broth at various temperatures, was simulated in scenarios with and without suppression by the microbiota of ground beef, also dominated by non-pathogenic pseudomonads (*Pseudomonas* spp.) as demonstrated for refrigerated retail raw milk (Liu et al., 2020).

Further, Coleman and colleagues (2003b) documented statistically significant differences in growth parameters for the pathogen *E. coli* O157:H7 in broth cultures based on two variables in predictive microbiology experiments that are of high relevance to raw milks: i) agitation or still culture; and ii) initial inoculum density (high density, ~1,000 cfu/mL; low density ~1 cfu/mL). An independent growth study is underway (FSNS, 2021) that will measure growth of all four pathogens at high (1,000 cfu/mL) and low (1-10 cfu/mL) inoculum levels in raw milk at 4.4°C that fills a significant gap in evidence required for QMRA noted by FSANZ in 2009.

EFSA also observed (2015, pg. 4) that the available QMRAs demonstrated that *L. monocytogenes* risk for raw milk ‘can be mitigated and reduced significantly if the cold chain is well controlled, the shelf-life of raw milk is limited to a few days and there is consumer compliance with these measures/controls.’ Given appropriate hygienic programs, no recent scientific evidence exists, to our knowledge, that demonstrates conclusively that raw milk is inherently dangerous though the presence of *L. monocytogenes* in raw milk is possible.

The recent scientific opinion by EFSA (2015) supports the need to update the Exposure Assessment for the FSANZ 2009 report, citing important data limitations for i) extrapolating data on prevalence and levels of pathogens in feces to milk; and ii) lack of validation of growth models derived from optimal nutrient broth and extrapolated to raw milk without adjusting for effects of the dense and diverse natural microbiota of raw milk.

EFSA (2019) subsequently considered application of Whole Genome Sequencing (WGS) to epidemiologic investigations, source attribution, and QMRA. The excerpt quoted below is from page 20 of this document.

‘Furthermore, the association of *L. monocytogenes* clones with different virulence potential with various food products (Maury et al., 2016; Njage et al., 2018) and different clinical outcomes (Njage et al., 2019) has been uncovered with the use of WGS. For STEC, associations between

genetic markers and (1) adhesive properties to human intestinal cells (Pielaat et al., 2015) and (2) clinical outcomes (Njage et al., 2019) have also been demonstrated.'

A more recent application of WGS to microbial risk assessment (Njage et al., 2020) provides yet another advancement in QMRA using -omics data. The researchers conclude that neglecting genetic and phenotypic heterogeneity of foodborne pathogens (as in the FSANZ 2009 approach) limits reliability of Exposure Assessment and Risk Characterization. The bias demonstrated by FSANZ likely overestimates risks by assuming no variability in pathogen strains or selecting outbreak strains for worst-case or fail-safe scenarios rather than accurately representing biological variability and constraints to pathogen growth.

### Considering Benefit-Risk

No application of formal methods for benefit-risk assessment (Fischhoff et al., 2011) has been completed for comparing benefits and risks of raw milk to date. However, many unfounded claims are made in literature reviews, including speculations that risks exceed benefits (Claeys et al., 2013; Davis et al., 2014; Lucey, 2015). Notably, these studies excluded emerging evidence of the dense and diverse natural microbiota of milks. The reviews include claims that actually represent merely opinions, with strong pro-pasteurization bias, that are not based on sound science, proper methodology, and rigorous and transparent analysis of both benefits and risks. One recent workshop proceeding paper (Verhagen et al., 2021) included an exploratory but incomplete assessment of benefits and risks for raw milk (vitamin B2 benefits compared to listeriosis risk) using quantitative methods for Disability Adjusted Life Years (DALYs) based on many unverified and infeasible assumptions.

Note that the Verhagen workshop paper did not consider multiple human clinical studies documenting benefits for significant reductions in inflammatory disease rates (allergy, asthma, eczema, inflammatory gut diseases; (Brick et al., 2016; House et al., 2017; Schröder et al., 2017; Abbring et al., 2018; Müller-Rompa et al., 2018; Abbring et al., 2019; Sozańska et al., 2019; Brick et al., 2020), respiratory and enteric diseases (Loss et al., 2015; Wyss et al., 2018), and neural diseases (Butler et al., 2020). The workshop report did not specify if both threshold and non-threshold dose-response models were applied as alternatives for immunocompetent and immunocompromised populations (Buchanan et al., 2017; Collineau et al., 2019). Neither did the workshop report discuss the current epidemiologic evidence for listeriosis and raw milk, nor the other three major foodborne pathogens causing campylobacteriosis, STEC illnesses, and salmonellosis. Thus, no application of formal methods for benefit-risk assessment to date has fully explored the large body of evidence currently available data for raw milk consumers around the world.

### Exposure Assessment Data-Gaps and Risk Management Policies

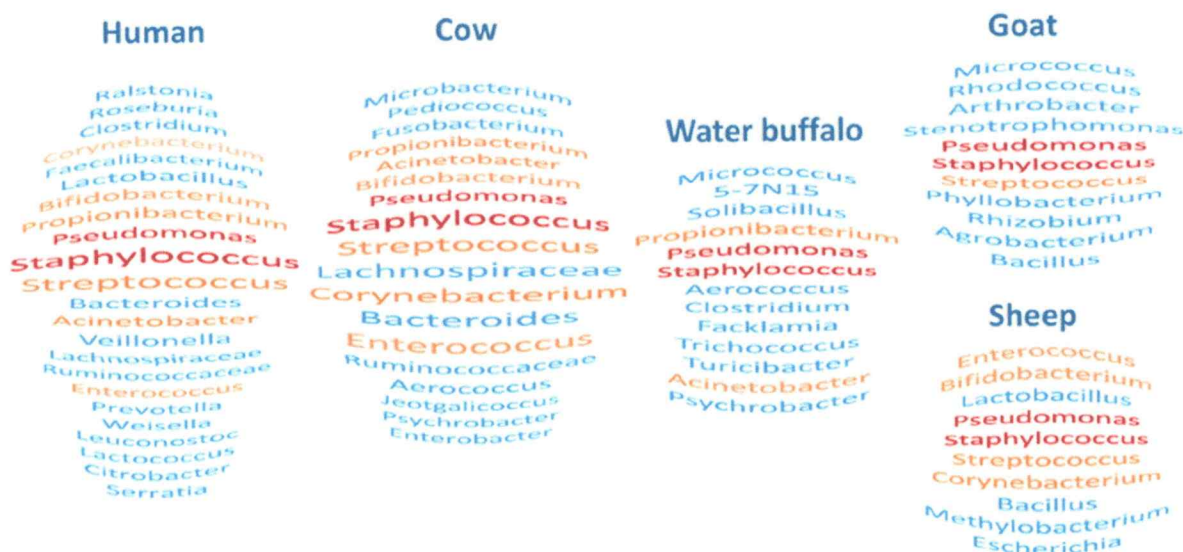
In the first decade of the 21<sup>st</sup> century, the human microbiome project was just beginning. Research using culture independent methods (genomics, proteomics, metabolomics, collectively termed -omics) revealed unanticipated complexities in mammalian milk ecosystems and unimagined tools to probe specific hypotheses concerning the composition, interactions, and functions of microbes in milks. Within another decade, the 'microbiome revolution' (Blaser, 2014) was dispelling long held assumptions about microbial communities (microbiomes) of humans and foods. Current -omics research challenges many previously unvalidated assumptions applied in QMRAs for raw milk.

Notably, even in 1999, well before the 'microbiome revolution' heralded by Professor Blaser (Blaser, 2014), the 'competing microflora' (now termed 'competing microbiota') of foods was endorsed by



international consensus as a relevant factor to be included in Exposure Assessment for QMRAs in its principles and guidelines document (CAC, 1999, pg. 4). By 2015 when the EFSA prepared its analysis of raw milk risk assessments including FSANZ (2009), this expert body also included a section on the microbial ‘flora’ of raw milk (now termed ‘milk microbiota’) and cited a 2013 study on the natural bovine milk microbiota (Quigley et al., 2013). Hundreds of peer-reviewed manuscripts on milk microbiota are now available, including recent reviews and studies that document the extent of research characterizing the microbes that dominate the milk microbiota (Wu et al., 2019; Breitenwieser et al., 2020; Oikonomou et al., 2020) previously believed to be sterile, including milks from humans and bovines. Yet, available QMRAs to date do not incorporate this crucial body of evidence for the impact of the raw milk microbiota depicted in Figure 12 that limits or prevents pathogen growth and survival. Similarly, epidemiologic studies on raw milk outbreak data do not cite or incorporate this body of evidence.

**Figure 12.** Major genera for the natural milk microbiota shared between various mammalian species (Oikonomou et al., 2020; authors Figure 2, page 4).



Of note, the figure above documents *Staphylococcus* as a common genera for natural raw milk microbiota of mammals, including milk from healthy humans and cows. Further, *Staphylococcus* spp. are described by FDA as ‘ubiquitous and impossible to eradicate in the environment’, as stated in the FDA Bad Bug Book (FDA, 2012). An opportunistic pathogen of this genus, *Staphylococcus aureus*, is also commonly present on skin, hair, and mucous membranes of the nasal passages and throats of healthy humans and cows (FDA, 2012; Food Standards Agency, 2017). Researchers from the U.S. National Institute of Health describe *S. aureus* as ‘one of the most infamous and widespread bacterial pathogens’ globally, particularly in health care, hospital-associated, or nosocomial infections, pneumonia, surgical site, prosthetic joint, and cardiovascular infections (Cheung et al., 2021). These researchers note that staphylococcal food poisoning (SFP) does occur, and cases are often self-limiting with recovery 1-3 days following onset of symptoms. Cases of systemic infections following SFP are very rare, unlike nosocomial infections, wound, and surgical infections (Cheung et al., 2021).

Although *S. aureus* may be commonly detected in raw milk, it rarely causes SFP in raw products, as it is recognized as a poor competitor in foods that is not known to form staphylococcal enterotoxins in properly refrigerated foods (FSAI, 2011). No cases were attributed to SFP in raw milk for two recent



CDC datasets from NORS: years 2005 through 2016 (Whitehead and Lake, 2018); and 2005 through 2019 (unpublished). When *S. aureus* levels exceed 100,000 pathogens per g or mL of food and temperature of the food exceeds 10°C or 50°F, staphylococcal enterotoxin may be formed that could cause food poisoning associated with ingestion of contaminated foods that contain high levels of preformed staphylococcal enterotoxins (Heidinger et al., 2009; FSAI, 2011; Schelin et al., 2011; FDA, 2012; FSA, 2017; Zeaki et al., 2019). Thus, demonstrating the presence of *S. aureus* in foods (including raw milk) and toxigenicity of foodborne strains do not provide sufficient evidence for potential to cause illness (FSAI, 2011; Zeaki et al., 2019). Due to its ubiquitous distribution, *S. aureus* may originate in food handlers, in foods, in livestock or pets, or from indoor or outdoor environments (air, dust, sewage, soil, surfaces, water; FDA, 2012), and the source of strains for clinical cases may not be identified in outbreak investigations.

Of the four states providing FOIA data on pathogens in raw milk from routine monitoring programs summarized herein, only NY state monitored for *S. aureus* and imposed a microbiological standard, though the standard selected was greater than zero (10,000 cfu/mL, Figure A-2.1, Appendix 2). All but one sample for NY state FOIA samples for this period were in compliance with the microbial standard, and one sample result was at the standard (10,000 cfu/mL). Further, one state (TX) monitored for presence of staphylococcal enterotoxin and detected it in 3 of 698 (0.5%) of raw milk samples analyzed in that period (Figure 6).

Multiple recent studies provide evidence for microbial competitions that reduce growth of *S. aureus*, toxin formation, and likelihood and severity of illness. Researchers demonstrated that eight microbes<sup>1</sup> co-inoculated into raw milk samples with a cocktail of *S. aureus* strains exhibited intermediate or strong antimicrobial activity against the pathogen following incubations of a simulated cheesemaking temperature profile (Aljasir and D'Amico, 2020). A companion study (Aljasir et al, 2020) identified synergistic combinations of protective microbes<sup>2</sup> that limited growth of other foodborne pathogens (*L. monocytogenes*, *Salmonella*, STECs) in the same simulated cheesemaking temporal profile. Even though the temperature profile for cheesemaking applied in these studies (35°C, 22°C, and 12°C) exceeds the refrigeration temperature of 4.4°C for raw foods recommended by FDA and USDA, combinations of microbes naturally present in the raw milk microbiota may similarly limit growth of pathogens including *S. aureus* and toxin formation at refrigeration temperatures. Evidence of human protection against *S. aureus* infections by probiotics (Kang et al., 2017; Khamash et al., 2018; Rao et al., 2021; Nataraj et al., 2021) and natural commensal *Staphylococcus* spp. (Shi et al., 2018) was cited in a case study for *S. aureus* included in a recent manuscript under review (Coleman et al., 2021).

Regarding Exposure Assessment data gaps, a pilot study is underway in an independent certified laboratory to estimate growth and survival of the four major raw milk pathogens in fresh raw milk incubated for 14 days at 4.4°C (FSNS, 2021). The study design is modeled after a growth study by Coleman and colleagues (2003b), including high and low pathogen inoculation levels, ~1,000 cfu/mL and ~1 cfu/mL, that significantly affected growth parameters for EHEC in culture broth. The refrigeration temperature selected for the current pilot study, 4.4°C or 40°F, is that recommended by FDA and USDA

<sup>1</sup> *Lactobacillus plantarum*; *Lb. rhamnosus*; *Lb. plantarum*; *Carnobacterium* spp.; *Lactococcus lactis* subsp. *lactis*; *Pediococcus acidilactici*; *Lb. curvatus*; *Hafnia alvei*

<sup>2</sup> *Lactococcus lactis* subsp. *Lactis*; *Pediococcus acidilactici*; *Lactobacillus curvatus*; *Lactobacillus plantarum*; *Lactobacillus rhamnosus*; *Lactobacillus plantarum*; *Carnobacterium* spp.; *Hafnia alvei*; *Enterococcus faecium*

to prevent growth of foodborne pathogens. These data will be important to consider in updating existing risk assessments that relied on pathogen growth data from optimal conditions as pure cultures in rich nutrient broths lacking the natural microbiota of raw milks that outcompete pathogens at the recommended refrigeration temperature (Coleman et al., 2003a; Oikonomou et al., 2020).

Fear and dread of many (or all) microbes as ‘germs’ that will kill us appear to factor strongly into policies requiring pasteurization and regulations on presence of potential pathogens, not their levels. The fear of microbes as ‘germs’ appears to entrench well-meaning scientists and regulators in misconceptions of 20<sup>th</sup> century science, and wall them off from any consideration of the tremendous advances in knowledge about the microbiota of milks, particularly the rich body of evidence for both benefits and risks of raw milks from both humans and cows. At present, the pasteurization and zero-tolerance policies for potential pathogens in raw milk appear inconsistent with the available evidence and the ‘state of the science’ in the 21<sup>st</sup> century.

Of note is recent work posing the question, should the concept of Recommended Daily Allowances (RDAs) for vitamins be expanded to RDAs for microbes (Hill, 2018; Marco et al., 2020). Functional foods that include natural microbes or starter cultures that ferment foods (e.g., cheese, kefir, kimchi, kombucha, raw milk, yoghurt) certainly could contribute to RDAs for microbes.

To provide context for the available microbiological data on Exposure Assessment, current epidemiologic evidence for U.S. dairy outbreaks from 2005 to 2019 from the Centers for Disease Control National Outbreak Reporting System (CDC NORIS) database are currently under review, and a manuscript will be in preparation shortly.

### **What Do Microbial Indicators Tell Us About Risk Assessment?**

Microbial indicators have been used in the dairy industry for nearly a century as evidence to evaluate adherence to proper hygiene and sanitation in food (and water) quality and adequacy of refrigeration. High levels of indicators (e.g., coliform counts exceeding 100 cfu/mL or SPCs exceeding 10,000 cfu/mL, USDA, 2019) may be indicative of poor sanitation or inadequate refrigeration, and may be correlated with low food quality, but are not necessarily predictive of public health concerns or food safety. From epidemiologic evidence of foodborne outbreaks across diverse foods, suspect foods containing detectable pathogens may also contain low numbers of microbial indicators.

Data for the following indicators in raw milk samples were provided by states under FOIA for the project described herein.

- Standard plate counts (SPCs) or total aerobic plate counts (APCs) or heterotrophic plate counts (HPCs) provide estimates of the total number of viable aerobic bacteria that can grow on a rich, unrestrictive nutrient media (plate count agar) at defined times and temperatures. A vast array of bacteria from many families and genera can grow on these plates. Bacteria requiring absence of oxygen (anaerobic) or lower levels of oxygen (micro-aerophilic), conditions typical of the gastrointestinal tract niches with limited oxygen, do not grow. Neither do microbes with more fastidious nutrient requirements grow on these plates, nor those less capable of outcompeting competitors. SPCs can be useful to predict time to spoilage, but these counts are not correlated to or predictive of specific pathogens that may cause disease.
- The coliform group is defined by growth of Gram-negative bacterial rods capable of fermenting lactose (including 19 genera, predominantly *Aeromonas*, *Citrobacter*, *Enterobacter*, *Escherichia*



including *E. coli*, *Hafnia*, *Klebsiella*, *Raoultella*, and *Serratia*) and quantified on specific nutrient media (typically brilliant green lactose bile broth, violet red bile agar, or MacConkey's agar) under aerobic conditions (in the presence of oxygen) at 32-35°C. Coliforms are detectable in various environmental sources (soil, water, air, vegetation including vegetables and silage, insects, feces). Many bacterial genera and species can grow on these plates, but these counts are not correlated to or predictive of specific pathogens that may cause disease.

- Generic *E. coli* are non-pathogenic Gram-negative bacterial rods typically present in the gut of mammals, in feces, and various environmental sources.

To our knowledge, microbial indicators in foods, water, and the environment are not predictive of the potential presence and level of pathogens. In contrast, some data exist for foodborne pathogens (*Campylobacter coli/jejuni*; *E. coli* O157:H7 (STECs/EHECs/VTECs); *Listeria monocytogenes*; *Salmonella*) as causing illness and severe illness based on levels or counts of pathogens estimated in challenge studies in human volunteers and animal model systems administered known pathogen doses, as discussed for Dose-Response Assessment above. Extensive data document the increasing likelihood and severity of illness with increasing dose of pathogens. Likelihood of disease and disease severity can be predicted for some pathogens based on data quantifying the dose-response relationships for immunocompetent and immunocompromised populations. If pathogens are present at sufficient levels to overwhelm innate human defenses (including the gut microbiota providing 'colonization resistance') and adaptive immunity (via specific antibodies) present from prior exposures or infections, disease can develop even in healthy people with competent immune systems. However, none of the states provided data quantifying counts of pathogens in raw milk for the four major foodborne pathogens, merely presence or absence of pathogens. In other words, the states impose 'zero tolerance' for the presence of pathogens that ignores decades of study and analysis of dose-response data necessary to estimate risk of illness.

For context, we note that the U.S. Grade A Pasteurized Milk Ordinance (2007) mandates milk quality testing by SPCs (and SCCs). Fresh unprocessed milk from clean, healthy cows that has been properly collected generally has SPCs <1,000 cfu/mL, while milk with SPCs exceeding 10,000 cfu/mL may indicate unsanitary procedures in milking or improper refrigeration (USDA Cooperative Extension, 2019). However, we are not aware of any data demonstrating higher risk of foodborne illness for raw milk samples at or exceeding SPC standards.

Limitations of the SPC method include: i) lack of identification of bacteria present and potential virulence in humans; ii) no information about source or identity of microbes predominating; and iii) incomplete count of microbes present that have more fastidious growth requirement, different optima for temperature and aerobicity than provided in test conditions.

The USDA Cooperative Extension Service (2019) notes that unsanitary milking practices, dirty equipment, contaminated water, dirty milking facilities, or milking cows with subclinical or clinical coliform mastitis are like when coliform counts exceed 100 cfu/mL. However, we are not aware of any data demonstrating higher risk of foodborne illness for raw milk samples at or exceeding the coliform standard.

Limitations of the coliform method are similar to those of SPCs: i) lack of identification of bacteria present and potential virulence in humans; ii) no information about source or identity of microbes



predominating; and iii) incomplete count of microbes present that have more fastidious growth requirement, different optima for temperature and aerobicity than provided in test conditions.

## CONCLUSIONS

The available evidence included in the Microsoft Access® database and other published and unpublished data falsify the assumption that raw milk is inherently dangerous and a major public health hazard. This database provides source data to inform future QMRAs and benefit-risk assessments.

## DEDICATION

This report is dedicated to the significant scientific contributions made by Dr. Theodore (Ted) Fairbank Beals, MD, in providing data and leadership on raw milk issues over much of his lifetime (1934-2021).

A highlight of Ted's contributions includes his leadership over 7 years of deliberations with the Michigan Fresh Unprocessed Whole Milk Workgroup, a group representing diverse perspectives on raw milk. The work culminated in a 101-page consensus report presented to the state Department of Agriculture and Rural Development in 2012. The extensive deliberations of the group led to opportunities for MI residents to engage in cow-share or herd-share agreements by which consumers could choose to obtain fresh unprocessed (raw) milk as a return on their investments in MI dairy farms.

We honor Ted and acknowledge his medical contributions, as well as his lifelong dedication to scientific integrity and bringing data to bear on misinformation. Ted contributed multiple articles to the WAPF journal *Wise Traditions* for the Real Milk Program, the last article only months before his death (Beals, 2021). Below are excerpts from Ted's obituary (<https://obits.mlive.com/us/obituaries/annarbor/-name/theodore-beals-obituary?pid=199896610>).

After retirement from his medical career, Ted brought together his academic and research training, dedication to scientific integrity, and specific knowledge of microbiology, testing, and cellular aspects of disease to bear on common misconceptions about unpasteurized milk. He was a lifelong advocate for organic principles, sustainable and local agriculture, and the nutritional and medical values of nutrient-dense foods. Ted was active in promoting the rights of farmers to provide, and consumers to obtain, milk and other locally-produced fresh unprocessed foods. ... Ted was respected by those he worked with, including those who did not agree with him.

## ACKNOWLEDGEMENTS

Weston A. Price Foundation provided the FOIA data obtained by Mr. Andras to CSC for this project. Aaron and Mark McAfee provided data from Organic Pastures, LLC, on their Test-and-Hold Program results and production of raw milk products for retail sale in CA. The British Columbia Herdshare Association provided data from its 'BC Fresh Milk Project.'

## REFERENCES

1. Abbring, S., Kusche, D., Roos, T.C., Diks, M. A., Hols, G., Garssen, J., ... & van Esch, B.C. (2019). Milk processing increases the allergenicity of cow's milk—Preclinical evidence supported by a human proof-of-concept provocation pilot. *Clinical & Experimental Allergy*, 49(7), 1013-1025.

2. Abbring, S., Verheijden, K.A., Diks, M.A., Leusink-Muis, A., Hols, G., Baars, T., Garssen, J, . . .  
 van Esch, B.C. (2018). Raw cow's milk prevents the development of airway inflammation in a  
 murine house dust mite-induced asthma model. *Frontiers in Immunology*, 8, 1045.
3. Aljasir, S. F., & D'Amico, D. J. (2020). The effect of protective cultures on *Staphylococcus*  
*aureus* growth and enterotoxin production. *Food Microbiology*, 91, 103541.
4. Aljasir, S. F., Gensler, C., Sun, L., & D'Amico, D. J. (2020). The efficacy of individual and  
 combined commercial protective cultures against *Listeria monocytogenes*, *Salmonella*, O157 and  
 non-O157 shiga toxin-producing *Escherichia coli* in growth medium and raw milk. *Food*  
*Control*, 109, 106924.
5. Amézquita-López BA, Soto-Beltrán M, Lee BG, Yambao JC, Quiñones B. (2018). Isolation,  
 genotyping and antimicrobial resistance of Shiga toxin-producing *Escherichia coli*. *Journal of*  
*Microbiology, Immunology and Infection* 51(4), 425-434.
6. Andras, D. (2015). Data provided by U.S. states in response to Freedom of Information Act  
 requests for microbiological results from state raw milk testing from June 1, 2009 to June 1,  
 2014. Personal communication via Weston A. Price Foundation, 6 July 2020.
7. Andrzejewska, M., Szczepańska, B., Śpica, D., & Klawe, J.J. (2019). Prevalence, virulence, and  
 antimicrobial resistance of *Campylobacter* spp. in raw milk, beef, and pork meat in Northern  
 Poland. *Foods*, 8(9), 420.
8. Beals, T. 2021. A Campaign for Real Milk. Observations on the collection of fresh unprocessed  
 milk samples from states regulating dairies: There are two kinds of milk. *Wise Traditions in*  
*Food, Farming, and the Healing Arts*, 22(2):97-100.
9. Berge, A.C., & Baars, T. (2020). Raw milk producers with high levels of hygiene and safety.  
*Epidemiology & Infection*, 148.
10. Bianchini, V., Borella, L., Benedetti, V., Parisi, A., Miccolupo, A., Santoro, E., ... & Luini, M.  
 (2014). Prevalence in bulk tank milk and epidemiology of *Campylobacter jejuni* in dairy herds in  
 Northern Italy. *Applied and Environmental Microbiology*, 80(6), 1832-1837.
11. Blaser, M. J. (2014). The microbiome revolution. *The Journal of Clinical Investigation*, 124(10),  
 4162-4165.
12. Breitenwieser, F., Doll, E. V., Clavel, T., Scherer, S., & Wenning, M. (2020). Complementary  
 use of cultivation and high-throughput amplicon sequencing reveals high biodiversity within raw  
 milk microbiota. *Frontiers in Microbiology*, 11, 1557.
13. Brick, T., Hettinga, K., Kirchner, B., Pfaffl, M. W., & Ege, M. J. (2020). The beneficial effect of  
 farm milk consumption on asthma, allergies, and infections: from meta-analysis of evidence to  
 clinical trial. *The Journal of Allergy and Clinical Immunology: In Practice*, 8(3), 878-889.
14. Brick T, Schober Y, Böcking C, Pekkanen J, Genuneit J, Loss G, Dalphin JC, Riedler J, Lauener  
 R, Nockher WA, Renz H, Vaarala O, Braun-Fahrlander C, von Mutius E, Ege MJ, Pfefferle PI;  
 Pasture study group. (2016).  $\omega$ -3 fatty acids contribute to the asthma-protective effect of  
 unprocessed cow's milk. *Journal of Allergy and Clinical Immunology*, 137(6):1699-1706.



15. Buchanan, R.L., Gorris, L.G., Hayman, M.M., Jackson, T.C., & Whiting, R.C. (2017). A review of *Listeria monocytogenes*: an update on outbreaks, virulence, dose-response, ecology, and risk assessments. *Food Control*, 75, 1-13.
16. Buffie CG, Bucci V, Stein RR, McKenney PT, Ling, L, Gobourne, A, ... Littmann E. 2015. Precision microbiome reconstitution restores bile acid mediated resistance to *Clostridium difficile*. *Nature* 517(7533), 205.
17. Butler, M.I., Bastiaanssen, T.F., Long-Smith, C., Berding, K., Morkl, S., Cusack, A.M., ... & Cryan, J. F. (2020). Recipe for a healthy gut: intake of unpasteurised milk is associated with increased lactobacillus abundance in the human gut microbiome. *Nutrients*, 12(5), 1468.
18. Cheung GYC, Bae JS, Otto M. (2021). Pathogenicity and virulence of *Staphylococcus aureus*. *Virulence*, 12(1):547-569. doi: 10.1080/21505594.2021.1878688. PMID: 33522395; PMCID: PMC7872022.
19. Claeys, W.L., Cardoen, S., Daube, G., De Block, J., Dewettinck, K., Dierick, K., ... & Herman, L. (2013). Raw or heated cow milk consumption: Review of risks and benefits. *Food Control*, 31(1), 251-262.
20. Castro, H., Ruusunen, M., & Lindström, M. (2017). Occurrence and growth of *Listeria monocytogenes* in packaged raw milk. *International Journal of Food Microbiology*, 261, 1-10.
21. Codex Alimentarius Commission (CAC). (1999). Principles and Guidelines for the Conduct of Microbiological Risk Assessment. (CAC/GL-30.) Available from: [http://www.codexalimentarius.net/download/standards/357/CXG\\_030e.pdf](http://www.codexalimentarius.net/download/standards/357/CXG_030e.pdf)
22. Coleman, M.E., Sandberg, S., & Anderson, S.A. (2003a). Impact of microbial ecology of meat and poultry products on predictions from exposure assessment scenarios for refrigerated storage. *Risk Analysis: An International Journal*, 23(1), 215-228.
23. Coleman, M.E., Tamplin, M.L., Phillips, J.G., & Marmer, B.S. (2003b). Influence of agitation, inoculum density, pH, and strain on the growth parameters of *Escherichia coli* O157: H7—relevance to risk assessment. *International Journal of Food Microbiology*, 83(2), 147-160.
24. Coleman ME, Marks HM, Hertzberg RC, Stephenson MM. (2017). Mechanistic modeling of salmonellosis: Update and future directions. *Human and Ecological Risk Assessment: An International Journal* 23(8):1830-56.
25. Coleman, M., Elkins, C., Gutting, B., Mongodin, E., Solano-Aguilar, G., & Walls, I. (2018). Microbiota and dose response: evolving paradigm of health triangle. *Risk Analysis*, 38(10), 2013-2028.
26. Coleman, M.E. (2021). CSC Report: Improving the Credibility of the Food Standards Australia New Zealand Report Entitled Microbiological Risk Assessment of Raw Cow Milk (2009) Considering New Evidence. Prepared for Australian Raw Milk Movement.
27. Coleman, M.E., Dietert, R.R., North, D.W., Stephenson, M. (2021). Enhancing human superorganism ecosystem resilience by holistically ‘managing our microbes’. Under review in *Applied Microbiology*.



28. Collineau, L., Boerlin, P., Carson, C.A., Chapman, B., Fazil, A., Hetman, B., ... & Smith, B.A. (2019). Integrating whole-genome sequencing data into quantitative risk assessment of foodborne antimicrobial resistance: a review of opportunities and challenges. *Frontiers in Microbiology*, 10, 1107.
29. Davis, B.J., Li, C.X., & Nachman, K. E. (2014). A Literature Review of the Risks and Benefits of Consuming Raw and Pasteurized Cow's Milk. A Response to the Request from The Maryland House of Delegates' Health and Government Operations Committee. John Hopkins Report, Maryland, USA.
30. Del Collo, L.P., Karns, J.S., Biswas, D., Lombard, J.E., Haley, B.J., Kristensen, R.C., ... & Van Kessel, J.A.S. (2017). Prevalence, antimicrobial resistance, and molecular characterization of *Campylobacter* spp. in bulk tank milk and milk filters from US dairies. *Journal of Dairy Science*, 100(5), 3470-3479.
31. Dicksved J, Ellström P, Engstrand L, Rautelin H. (2014). Susceptibility to *Campylobacter* infection is associated with the species composition of the human fecal microbiota. *MBio*, 5(5), e01212-14.
32. Dietert, R.R. (2016). *The Human Superorganism: How the Microbiome is Revolutionizing the Pursuit of a Healthy Life*. Dutton, New York, New York. 341 p.
33. Dietert RR. (2017a). Safety and risk assessment for the human superorganism. *Human and Ecological Risk Assessment* 23(8):1819-1829.
34. Dietert RR. (2017b). The microbiome-immune-host defense barrier complex (microimmunosome) and developmental programming of noncommunicable diseases. *Reproductive Toxicology* 68:49-58.
35. Dietert RR. (2018). A Focus on Microbiome Completeness and Optimized Colonization Resistance in Neonatology. *NeoReviews* 19(2):e78-88.
36. EFSA Panel on Biological Hazards. (2015). Scientific opinion on the public health risks related to the consumption of raw drinking milk. *EFSA Journal*, 13(1), 95.
37. European Food Safety Authority Panel on Biological Hazards (EFSA BIOHAZ Panel), Koutsoumanis, K., Allende, A., Alvarez-Ordóñez, A., Bolton, D., Bover-Cid, S., ... & Lindqvist, R. (2019). Whole genome sequencing and metagenomics for outbreak investigation, source attribution and risk assessment of food-borne microorganisms. *EFSA Journal*, 17(12), e05898.
38. Grade A Pasteurized Milk Ordinance (2007) Revision. U. S. Department of Health and Human Services, Public Health Service, Food and Drug Administration.
39. Fischhoff, B., Brewer N.T., & Downs, J.S. (2011). *Communicating Risks and Benefits: An Evidence-Based User's Guide*. Government Printing Office.
40. FAO/WHO STEC Expert Group. (2019). Hazard identification and characterization: Criteria for categorizing Shiga toxin-producing *Escherichia coli* on a risk basis. *J Food Protection* 82(1):14.
41. Food and Drug Administration, Center for Food Safety and Applied Nutrition, U.S. Department of Health and Human Services / Food Safety and Inspection Service, & U.S. Department of Agriculture [FDA/FSIS]. (2003). Interpretive summary: Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* among Selected Categories of

Ready-to-Eat Foods. Retrieved from <https://www.fda.gov/food/cfsan-risk-safety-assessments/quantitative-assessment-relative-risk-public-health-foodborne-listeria-monocytogenes-among-selected>.

42. FDA (2012). Bad Bug Book, Foodborne Pathogenic Microorganisms and Natural Toxins. Second Edition. Retrieved from <https://www.fda.gov/food/foodborne-pathogens/bad-bug-book-second-edition>.
43. Food Safety Authority of Ireland (FSAI) (2011). Microbial Factsheet Series: *Staphylococcus aureus*. Retrieved from <https://www.fsai.ie/staphylococcusaureus.html>.
44. Food Safety Net Services (FSNS). (2021). Determination of Growth Rate of *Salmonella enterica* spp., *E. coli* O157:H7, *Campylobacter* spp., and *Listeria monocytogenes* in Raw Milk. Protocol with study design will be provided upon request to [peg@colemanscientific.org](mailto:peg@colemanscientific.org).
45. Food Standards Agency (FSA). (2017). Risk Assessment on Meticillin-Resistant *Staphylococcus aureus* (MRSA), with a focus on Livestock-associated MRSA in UK Food Chain. Retrieved from [https://www.food.gov.uk/sites/default/files/media/document/mrsa\\_risk\\_assessment\\_feb17\\_0.pdf](https://www.food.gov.uk/sites/default/files/media/document/mrsa_risk_assessment_feb17_0.pdf).
46. Food Standards Australia New Zealand (FSANZ). (2009). Microbial Risk Assessment of Raw Cow Milk. Retrieved from <https://www.foodstandards.gov.au/code/proposals/documents/-P1007%20PPPS%20for%20raw%20milk%201AR%20SD1%20Cow%20milk%20Risk%20Assessment.pdf>.
47. Giacometti, F., Serraino, A., Finazzi, G., Daminelli, P., Losio, M.N., Arrigoni, N., ... & Zanoni, R. G. (2012). Sale of raw milk in northern Italy: Food safety implications and comparison of different analytical methodologies for detection of foodborne pathogens. *Foodborne Pathogens and Disease*, 9(4), 293-297.
48. Giacometti, F., Bonilauri, P., Serraino, A., Peli, A., Amatiste, S., Arrigoni, N., ... & Bolzoni, G. (2013). Four-year monitoring of foodborne pathogens in raw milk sold by vending machines in Italy. *Journal of Food Protection*, 76(11), 1902-1907.
49. Giacometti F, Bonilauri P, Piva S, Scavia G, Amatiste S, Bianchi DM, Losio MN, Bilei S, Cascone G, Comin D, Daminelli P. (2017). Paediatric HUS cases related to the consumption of raw milk sold by vending machines in Italy: quantitative risk assessment based on *Escherichia coli* O157 official controls over 7 years. *Zoonoses Public Health* 4(7):505-16.
50. Hanson H, Whitfield Y, Lee C, Badiani T, Minielly C, Fenik J, Makrotergios T, Kopko C, Majury A, Hillyer E, Fortuna L. (2019). *Listeria monocytogenes* associated with pasteurized chocolate milk, Ontario, Canada. *Emerging Infectious Diseases* 5(3):581.
51. Heidinger, J. C., Winter, C. K., & Cullor, J. S. (2009). Quantitative microbial risk assessment for *Staphylococcus aureus* and *Staphylococcus enterotoxin A* in raw milk. *Journal of Food Protection*, 72(8), 1641-1653.
52. Hill, C. (2018). RDA for microbes—are you getting your daily dose? *The Biochemist*, 40(4), 22-25.



53. House, J.S., Wyss, A.B., Hoppin, J.A., Richards, M., Long, S., Umbach, D.M., ... & Barker-Cummings, C. (2017). Early-life farm exposures and adult asthma and atopy in the Agricultural Lung Health Study. *Journal of Allergy and Clinical Immunology*, 140(1), 249-256.
54. Jaros, P., Cogger, N., & French, N.P. (2008). A Systematic Review of the Human Disease Evidence Associated with the Consumption of Raw Milk and Raw Milk Cheeses. A Report Prepared for the New Zealand Food Safety Authority (NZFSA). Retrieved from: <https://www.mpi.govt.nz/dmsdocument/22309/direct>.
55. Jaakkonen, A., Castro, H., Hallanvuori, S., Ranta, J., Rossi, M., Isidro, J., ... & Hakkinen, M. (2019). Longitudinal study of Shiga toxin-producing *Escherichia coli* and *Campylobacter jejuni* on Finnish dairy farms and in raw milk. *Applied and Environmental Microbiology*, 85(7).
56. Jackson, E.E., Erten, E.S., Maddi, N., Graham, T.E., Larkin, J.W., Blodgett, R.J., ... & Reddy, R.M. (2012). Detection and enumeration of four foodborne pathogens in raw commingled silo milk in the United States. *Journal of Food Protection*, 75(8), 1382-1393.
57. Kampmann C, Dicksved J, Engstrand L, Rautelin H. (2016). Composition of human faecal microbiota in resistance to *Campylobacter* infection. *Clinical Microbiology and Infection* 22(1), 61-e1.
58. Kang, M. S., Lim, H. S., Oh, J. S., Lim, Y. J., Wuertz-Kozak, K., Harro, J. M., ... & Achermann, Y. (2017). Antimicrobial activity of *Lactobacillus salivarius* and *Lactobacillus fermentum* against *Staphylococcus aureus*. *Pathogens and Disease*, 75(2).
59. Khamash DF, Voskertchian A, Milstone AM. Manipulating the microbiome: evolution of a strategy to prevent *S. aureus* disease in children. *J Perinatol*. 2018 Feb;38(2):105-109. doi: 10.1038/jp.2017.155. Epub 2017 Nov 9. PMID: 29120455; PMCID: PMC5790614.
60. Kiel M, Sagory-Zalkind P, Miganeh C, Stork C, Leimbach A, Sekse C, ... Dobrindt U. (2018). Identification of novel biomarkers for priority serotypes of Shiga toxin-producing *Escherichia coli* and the development of multiplex PCR for their detection. *Frontiers in Microbiology*, 9, 1321.
61. Lambertini E, Karns JS, Van Kessel JAS, Cao H, Schukken YH, Wolfgang DR, ... Pradhan AK. (2015). Dynamics of *Escherichia coli* virulence factors in dairy herds and farm environments in a longitudinal study in the United States. *Appl. Environ. Microbiol.*, 81(13), 4477-4488.
62. Latorre, A.A., Pradhan, A.K., Van Kessel, J.A., Karns, J.S., Boor, K.J., Rice, D.H., ... & Schukken, Y.H. (2011). Quantitative risk assessment of listeriosis due to consumption of raw milk. *Journal of Food Protection*, 74(8), 1268-1281.
63. Liu, J., Zhu, Y., Jay-Russell, M., Lemay, D. G., & Mills, D. A. (2020). Reservoirs of antimicrobial resistance genes in retail raw milk. *Microbiome*, 8(1), 1-15.
64. Loss, G., Depner, M., Ulfman, L.H., Van Neerven, R.J., Hose, A.J., Genuneit, J., ... & Ege, M. J. (2015). Consumption of unprocessed cow's milk protects infants from common respiratory infections. *Journal of Allergy and Clinical Immunology*, 135(1), 56-62.
65. Lucey, J.A. (2015). Raw milk consumption: risks and benefits. *Nutrition Today*, 50(4), 189.



66. Marco, M.L., Hill, C., Hutkins, R., Slavin, J., Tancredi, D.J., Merenstein, D., & Sanders, M.E. (2020). Should there be a recommended daily intake of microbes? *The Journal of Nutrition*, 150(12), 3061-3067.
67. Marks H.M., Coleman M.E., Lin C.-T.J., & Roberts T. (1998). Topics in microbial risk assessment: Dynamic flow tree modeling. *Risk Analysis*, 18(3):309-328.
68. Marshall, J.C., Soboleva, T.K., Jamieson, P., & French, N.P. (2016). Estimating bacterial pathogen levels in New Zealand bulk tank milk. *Journal of Food Protection*, 79(5), 771-780.
69. Maury, M. M., Tsai, Y. H., Charlier, C., Touchon, M., Chenal-Francisque, V., Leclercq, A., ... & Lecuit, M. (2016). Uncovering *Listeria monocytogenes* hypervirulence by harnessing its biodiversity. *Nature Genetics*, 48(3), 308.
70. McLauchlin, J., Aird, H., Elliott, A., Forester, E., Jørgensen, F., & Willis, C. (2020). Microbiological quality of raw drinking milk and unpasteurised dairy products: Results from England 2013–2019. *Epidemiology and Infection*, 148.
71. Monge S, Teunis P, Friesema I, Franz E, Ang W, van Pelt W, Mughini-Gras L. (2018). Immune response-eliciting exposure to *Campylobacter* vastly exceeds the incidence of clinically overt campylobacteriosis but is associated with similar risk factors: A nationwide serosurvey in the Netherlands. *Journal of Infection*, 77(3), 171-177.
72. Müller-Rompa, S.E., Markevych, I., Hose, A.J., Loss, G., Wouters, I.M., Genuneit, J., Braun-Fahrlander, C., . . . von Mutius, E. (2018). An approach to the asthma-protective farm effect by geocoding: Good farms and better farms. *Pediatric Allergy and Immunology* 29(3), 275-282.
73. Nataraj BH, Ramesh C, Mallappa RH. Extractable surface proteins of indigenous probiotic strains confer anti-adhesion knock and protect against Methicillin-resistant *Staphylococcus aureus* induced epithelial hyperpermeability in HT-29 cell line. *Microb Pathog*. 2021 May 17:104974. doi: 10.1016/j.micpath.2021.104974. Epub ahead of print. PMID: 34015494.
74. Njage, P. M. K., Henri, C., Leekitcharoenphon, P., Mistou, M. Y., Hendriksen, R. S., & Hald, T. (2018). Machine learning methods as a tool for predicting risk of illness applying next-generation sequencing data. *Risk Analysis*, 39(6), 1397-1413.
75. Njage, P. M. K., Leekitcharoenphon, P., & Hald, T. (2019). Improving hazard characterization in microbial risk assessment using next generation sequencing data and machine learning: predicting clinical outcomes in shigatoxigenic *Escherichia coli*. *International Journal of Food Microbiology*, 292, 72-82.
76. Njage, P. M. K., Leekitcharoenphon, P., Hansen, L. T., Hendriksen, R. S., Faes, C., Aerts, M., & Hald, T. (2020). Quantitative microbial risk assessment based on whole genome sequencing data: case of *Listeria monocytogenes*. *Microorganisms*, 8(11), 1772.
77. National Research Council (NRC). (1996). Understanding risk: Informing Decisions in a Democratic Society. National Academies Press.

78. NY State Department of Agriculture and Markets. 2007. Raw Milk Sales – Startup and Guidance, including Quality Standards. Retrieved from <https://agriculture.ny.gov/system/files/documents/2020/10/rawmilksalesstartupandguidance.pdf>.
79. Oikonomou, G., Addis, M. F., Chassard, C., Nader-Macias, M. E. F., Grant, I., Delbès, C., ... & Even, S. (2020). Milk microbiota: What are we exactly talking about? *Frontiers in Microbiology*, 11, 60.
80. Pielat, A., Boer, M. P., Wijnands, L. M., van Hoek, A. H., Bouw, E., Barker, G. C., ... & Franz, E. (2015). First step in using molecular data for microbial food safety risk assessment; hazard identification of *Escherichia coli* O157: H7 by coupling genomic data with in vitro adherence to human epithelial cells. *International Journal of Food Microbiology*, 213, 130-138.
81. Pouillot R, Klontz KC, Chen Y, Burall LS, Macarasin D, Doyle M, Bally KM, Strain E, Datta AR, Hammack TS, Van Doren JM. (2016). Infectious dose of *Listeria monocytogenes* in outbreak linked to ice cream, United States, 2015. *Emerging Infectious Diseases* 22(12):2113.
82. Powell, M. R., Ebel, E., Schlosser, W., Walderhaug, M., & Kause, J. (2000). Dose-response envelope for *Escherichia coli* O157: H7. *Quantitative Microbiology*, 2(2), 141-163.
83. Quigley L., O'Sullivan O., Stanton C., Beresford T.P., Ross R.P., Fitzgerald G.F., & Cotter P.D. (2013). The complex microbiota of raw milk. *FEMS Microbiology Reviews*, 37:664-698.
84. Rao C, Coyte KZ, Bainter W, Geha RS, Martin CR, Rakoff-Nahoum S. Multi-kingdom ecological drivers of microbiota assembly in preterm infants. *Nature*. 2021 Mar;591(7851):633-638. doi: 10.1038/s41586-021-03241-8. Epub 2021 Feb 24. PMID: 33627867; PMCID: PMC7990694.
85. Ricchi, M., Scaltriti, E., Cammi, G., Garbarino, C., Arrigoni, N., Morganti, M., & Pongolini, S. (2019). Persistent contamination by *Listeria monocytogenes* of bovine raw milk investigated by whole-genome sequencing. *Journal of Dairy Science*, 102(7), 6032-6036.
86. Schelin, J., Wallin-Carlquist, N., Thorup Cohn, M., Lindqvist, R., & Barker, G. C. (2011). The formation of *Staphylococcus aureus* enterotoxin in food environments and advances in risk assessment. *Virulence*, 2(6), 580-592.
87. Schröder, P. C., Illi, S., Casaca, V. I., Lluís, A., Boeck, A., Roduit, C., ... & Roponen, M. (2017). A switch in regulatory T cells through farm exposure during immune maturation in childhood. *Allergy*, 72(4), 604-615.
88. Shi, B., Leung, D. Y., Taylor, P. A., & Li, H. (2018). MRSA colonization is associated with decreased skin commensal bacteria in atopic dermatitis. *The Journal of Investigative Dermatology*, 138(7), 1668.
89. Sorbara MT, Pamer EG. (2019). Interbacterial mechanisms of colonization resistance and the strategies pathogens use to overcome them. *Mucosal Immunology* 12(1): 1–9. doi:10.1038/s41385-018-0053-0
90. Sozańska, B. (2019). Raw cow's milk and its protective effect on allergies and asthma. *Nutrients*, 11(2), 469.



91. Stasiewicz, M.J., Martin, N., Laue, S., Gröhn, Y.T., Boor, K.J., & Wiedmann, M. (2014).  
 Responding to bioterror concerns by increasing milk pasteurization temperature would increase  
 estimated annual deaths from listeriosis. *Journal of Food Protection*, 77(5), 696-705.
92. Stein RR, Bucci V, Toussaint NC, Buffie CG, Räscht G, Pamer EG, Sander C, Xavier JB. (2013).  
 Ecological modeling from time-series inference: Insight into dynamics and stability of intestinal  
 microbiota. *Public Library of Science Computational Biology* 9(12):e1003388.
93. Trevisani, M., Mancusi, R., Riu, R., & Serraino, A. (2013). Quantitative detection of Shiga toxin-  
 producing and enteropathogenic *Escherichia coli* serotypes O157 and O26 in bulk raw milk. *Food*  
*Analytical Methods*, 6(6), 1750-1758.
94. Tribble DR, Baqar S, Scott DA, Oplinger ML, Trespalacios F, Rollins D, ... Burg EF. (2010).  
 Assessment of the duration of protection in *Campylobacter jejuni* experimental infection in  
 humans. *Infection and Immunity* 78(4), 1750-1759.
95. USDA Cooperative Extension. (2019). How Milk Quality is Assessed. Retrieved from  
<https://dairy-cattle.extension.org/how-milk-quality-is-assessed/>.
96. Verhagen, H., Alonso-Andicoberry, C., Assunção, R., Cavaliere, F., Eneroth, H., Hoekstra, J., ...  
 & Cozzini, P. (2021). Risk-benefit in food safety and nutrition—Outcome of the 2019 Parma  
 Summer School. *Food Research International*, 141, 110073.
97. Whitehead, J., & Lake, B. (2018). Recent trends in unpasteurized fluid milk outbreaks,  
 legalization, and consumption in the United States. *PLoS Currents*, 10.
98. Wu, H., Nguyen, Q. D., Tran, T. T., Tang, M. T., Tsuruta, T., & Nishino, N. (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.
99. Wyss, A. B., House, J. S., Hoppin, J. A., Richards, M., Hankinson, J. L., Long, S., ... & London,  
 S. J. (2018). Raw milk consumption and other early-life farm exposures and adult pulmonary  
 function in the Agricultural Lung Health Study. *Thorax*, 73(3), 279-282.
100. Zeaki, N., Johler, S., Skandamis, P. N., & Schelin, J. (2019). The role of regulatory  
 mechanisms and environmental parameters in staphylococcal food poisoning and resulting  
 challenges to risk assessment. *Frontiers in Microbiology*, 10, 1307.

## APPENDIX 1. CSC Expertise in Database Support and Medical Microbiology

**Michele Stephenson** is an expert in database design and support. She has over 16 years of database use, development, and analysis experience. At a past position, she developed Microsoft Access® databases for the US Environmental Protection Agency, FBI, and other government agencies. One of these databases has a web interface via an SQL server. She currently is part of the technical systems and services division at Syracuse University. She provides technical support and training on the Blackbaud® Constituent Relationship Management system. Some of her database management responsibilities have included storing, organizing, presenting, using, and analyzing data. She has a thorough understanding of how to write reports and queries using the database tools along with and copying data into Microsoft Excel® or other types of formats to analyze them further using charts and graphs.

**Margaret (Peg) Coleman** is a medical microbiologist and microbial risk assessor who was selected as a Fellow of the Society for Risk Analysis in 2020, following 25 years of research and professional service in quantitative microbial risk assessment (QMRA). She began serving in the US federal government (USDA/FSIS/Risk Assessment and Epidemiology Division) in 1988 and studied at University of Georgia's College of Veterinary Medicine in 1992. She continued that microbial risk work as founder of the woman-owned small business Coleman Scientific Consulting in 2010. Her extensive interdisciplinary work in QMRA is widely published in risk and microbiology journals. She contributed to the first QMRA study on the bacterial pathogen *Escherichia coli* O157:H7 in ground beef in the journal *Risk Analysis* (Marks et al., 1998) and the subsequent USDA/FSIS QMRA report on *E. coli* O157:H7 in ground beef (2001). She continues to serve in leadership roles in professional organizations, including the Society for Risk Analysis (SRA). Ms. Coleman is a founding member of the SRA Microbial Risk Analysis Specialty Group and current President of Upstate NY SRA. She also served as her Agency representative on the Codex Alimentarius Commission committee that developed the Principles and Guidelines for the Conduct of Microbiological Risk Assessment in the international arena. The guidelines document was finalized in 1999 under expedited review (CAC, 1999).

Her clients recognize her as a senior level microbiologist and key member of interdisciplinary teams, a trusted advisor, an invited expert and educator, and a thorough peer-reviewer for methodology and case studies that assess microbial and chemical risks. Her unique interdisciplinary knowledge and leadership were essential for interdisciplinary teams to develop coherent models that reflect biologically relevant data and the uncertainties for determining the significant factors contributing to the underlying causal mechanisms for human health risks. Many assessments incorporated her insights from environmental and food chain exposures to pathogens from scenarios for intentional bioterror attacks and natural farm to fork systems. Her work continues to raise challenges to use of outdated conservative assumptions inconsistent with advancing genomic knowledge of microbiota in foods and human gastrointestinal tracts.

Innovative recent projects apply knowledge emerging from culture-independent studies of microbial genes or molecules produced by microbes to assess predictable effects of the complex communities of microbes in foods and humans, both benefits and risks. Her recent manuscripts in the prestigious journals *Human and Ecological Risk Assessment* and *Risk Analysis* challenge outdated assumptions for each aspect of QMRA (hazard identification, exposure assessment, hazard characterization, and risk characterization) for microbial pathogens. Current resume for Ms. Coleman is appended herein.



## Medical Microbiologist/Risk Analyst

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### Career Summary

- Trans-disciplinary scientist and Fellow of the Society for Risk Analysis (SRA), recognized by my peers for significant accomplishments in microbial benefit-risk analyses and extensive professional service in leadership, education, and mentoring in risk analysis:
  - infectious diseases transmitted in air, food, and water or via contact, including anthrax, campylobacteriosis, cholera, COVID-19, entero-pathogenic *E. coli* diseases, listeriosis, salmonellosis, tularemia
  - opportunistic infections including *Clostridium difficile* and pseudomonads
  - beneficial microbes enhancing gut or immune system function
- Invited expert on multiple projects with National Academy of Sciences committees and government agencies in the US and abroad to:
  - develop comprehensive, defensible risk assessments from ingestion and inhalation of microbial pathogens and non-pathogens
  - improve scientific support and risk analysis methodology and practice
  - provide peer-review for microbial risk reports and tools
- Educator in risk analysis (assessment, communication, management) and cycles of analysis and deliberation (analytic-deliberative process) to support transparent science-based decisions
- Leader in advancing development of coherent empirical and mechanistic models for more robust microbial risk analysis that accounts for variabilities and dependencies of complex systems particularly the gut microbiota in healthy and immunocompromised hosts

### Areas of Expertise

- Expert testimony, conduct and peer-review microbial benefit and risk analysis
- Microbial ecology, predictive microbiology, public health
- Peer review and education

### Education

- |                              |  |
|------------------------------|--|
| • MS in Medical Microbiology | 1995 (University of Georgia)   |
| • MS in Biology/Biochemistry | 1988 (Utah State University)   |
| • BS in Biology/Chemistry    | 1979 (SUNY College of Environmental Science & Forestry and Syracuse University, cum laude) |

## Summary of Qualifications

### Microbial Risk Assessor

- As a scientist in the consulting industry, previously in US federal government, I lead and participate on trans-disciplinary teams that evaluate evidence and assess risks associated with air-borne, food-borne, and water-borne pathogens from natural and intentional releases
- My publications in microbial risk include assessments on:
  - Benefit-Risk analysis for raw breastmilk microbiota in *Applied Microbiology*
  - Microbiome and Dose-Response in *Risk Analysis*; Microbiome and foodborne and respiratory risk assessment in *Applied Microbiology*
  - Salmonellosis in *Foodborne Pathogens & Disease, Human & Ecological Risk Assessment, J Food Protection, Quantitative Microbiology, Risk Analysis, Veterinary Pathology*
  - Growth of multiple pathogens including *Campylobacter*, *E. coli* O157:H7, *Listeria*, and *Salmonella* species in single and mixed populations in *Risk Analysis, J Food Protection*
  - Empirical and mechanistic modeling for multiple pathogens including *Salmonella* and *Campylobacter* in *J Toxicology and Environmental Health, Quantitative Microbiology*
  - Anthrax and tularemia in *Biothreat and Biosecurity and Risk Analysis*
  - Kinetics of immunological interactions of complement in *Blood*
  - Listeriosis in *J Food Protection*
  - Microbial ecology of the respiratory and gastrointestinal tracts in *Applied and Environmental Microbiology, Human and Ecological Risk Assessment, Risk Analysis*
  - Qualitative and quantitative risk assessment in *Food Control*
  - Science and risk assessment in *Human and Ecological Risk Assessment and Risk Analysis*
  - Variability in pathogen growth in *International J Food Microbiology*

### Subject Matter Expert for Medical Microbiology and Microbial Risk Analysis

- Provide expert advice, analysis, and peer review of microbial risk assessment reports and software for agency, inter-agency, national, and international clients, as well as expert testimony for science-based legal challenges
- Invited participant at workshops on risk assessment and risk management, including national and international work groups convened by the Codex Committee on Food Hygiene, the U.S. Interagency Risk Assessment Consortium, the International Life Sciences Institute (North America and Europe), and the U.S. National Academies of Sciences, Engineering, Medicine
- Invited reviewer for scientific journals and grants

## Boards and Professional Affiliations

- Alliance for Risk Assessment (ARA; invited member of Science Panel, 2020)
- American Society for Microbiology (ASM; 1996 – present)



- Interagency Risk Assessment Consortium (iRAC), Founding Member (1998 – 2004)
- Raw Milk Institute (RAWMI), Advisory Board Member (July 2019 – present); Board of Directors Member (January – June, 2019)
- Society of Federal Health Professionals (AMSUS; 2014 – 2016)
- Society for Risk Analysis (SRA), member (1996 – present)
  - Fellow of SRA (2020)
  - Editorial Board member for SRA journal *Risk Analysis* (2006 – 2018)
  - Secretary/Treasurer Dose-Response Specialty Group (2019 – 2020)
- SUNY College of Environmental Science and Forestry Alumni Board, Member (2010 – present)
- SUNY Upstate Medical University Master of Public Health Board, Member (2011 – 2016)
- Upstate NY SRA, founder, and current President (2005 – present)

## Honors and Awards

- **2020:** Fellow of the Society for Risk Analysis
- **2011:** National Association of Professional Women award as woman of the year for professional excellence in scientific consulting
- **2007:** SRC leadership award, preparing/publishing multidisciplinary risk analysis
- **2003:** USDA/FSIS Spot Award, excellent work associated with cooperation between Risk Assessment Division and other Risk Assessment Consortium members
- **2001:** FDA Group Award as a member of the *Listeria monocytogenes* Risk Assessment Group for outstanding contributions to the FDA and USDA/FSIS public health protection through the development of the *Listeria monocytogenes* risk assessment
- **1998:** USDA/FSIS Spot Awards for: providing time and expertise to the FSIS CORE Business Process Project on Assess Risk; and special service act in support of project on risk analysis for pre-mature browning of hamburger
- **1998:** FDA Group Recognition Award for exceptional contributions towards improvements in the field of microbial risk assessment and for forging improved inter-agency collaborations
- **1997:** USDA/FSIS Certificate of Merit for outstanding performance in improving the capability of FSIS to use risk analysis to improve food safety and reduce foodborne disease
- **1996:** USDA/ORACBA Certificate of Appreciation, USDA Risk Assessment Workshop lecture

## Expert Testimony for Court Cases and Petitions

- **2021.** CSC Report: Improving the Credibility of the Food Standards Australia New Zealand Report Entitled Microbiological Risk Assessment of Raw Cow Milk (2009) Considering New Evidence (Australian Raw Milk Movement, Incorporated)
- **2019 – 2020:** Testimony for Carlow Farmhouse Cheese vs Department of Agriculture Food and Marine/Food Safety Authority of Ireland (High Court of Ireland)
- **2019:** Testimony for Lystn LLC/Answers Pet Food vs FDA/AAFCO/ Colorado Department Agriculture/et al. (US District Court for the District of Colorado, CIV. NO. 19-CV-1943)

- **2018 – 2020:** Testimony and technical assistance for Glencolton Farm/Affleck et al. vs Attorney General of Ontario/Canada (Ontario Superior Court of Justice, Court File No.: CV-18-591774)
- **2017:** Scientific support for US FDA request for information on raw cheese
- **2016, 2020:** Scientific support for petition of US FDA to permit interstate sale of raw butter

## Reviewer

- *CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition, Natural Resources*
- *Critical Reviews in Food Science and Nutrition*
- *Infectious Diseases: Research and Treatment*
- *Journal of Exposure Science and Environmental Epidemiology*
- *Journal of Food Protection*
- *Journal of Food Science*
- *Quantitative Microbiology*
- *Risk Analysis*

## Professional Highlights

### **Coleman Scientific Consulting, Groton, NY (2010 – present)**

- Operate woman-owned small business as sole proprietor, providing multidisciplinary decision support for practical solutions balancing benefits and risks for exposures to microbes
- Prepare, submit technical manuscripts on microbial benefits, risks, for peer-review in journals including *Applied Microbiology*, *Human and Ecological Risk Assessment*, and *Risk Analysis*
- Provide expert testimony, technical advice and scientific support to clients, many of whom request multiple contract years of support. Scientific support for one client on derivation of ‘safe’ exposure guidelines for biological threats inhaled or ingested by humans and extended for more than 10 years, another on benefits and risks of natural microbiota of foods for more than 3 years
- Serve as peer reviewer for three journals (*CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition, and Natural Resources*; *Journal of Exposure Science and Environmental Epidemiology*; *Risk Analysis*) and served as consultant, peer reviewer, and committee member for US clients including the Army, EPA, FDA, the National Academies of Science, and USDA
- Deliver presentations, briefings, and lectures on benefits and risks of microbes, including interactions of microbes with innate immune systems, for organizations including the American Association for the Advancement of Science, Weston A. Price Foundation (Wise Traditions Conference), SRA, federal Interagency Risk Assessment Consortium, and SUNY ESF
- Provide teaching and leadership expertise to academic and professional organizations including SUNY ESF and Upstate NY SRA, past leadership to Upstate Medical University’s Master of Public Health program and the National Academies of Science
- Organize projects on microbial risks and benefits, including first crowdfunding campaign through Upstate NY SRA supporting preparation of manuscripts submitted for peer review. Joint



SRA project on Microbiota of Milks began with partnering regional organizations of SRA, Australia/New Zealand, New England, and Upstate NY

- Provided technical support to US federal government client for report and manuscript documenting time- and dose-dependent models for aerosolized bacterial spores administered in single and multiple doses to rabbits
- Provided medical microbiology services for international client with responsibility to conduct screening assessments for safety of micro-organisms including pseudomonads released into the environment prior to development of quantitative microbial risk assessment methodologies
- Prepared position papers on risk of human health effects from dermal exposure to bacterial spores and use of remote sensing and climate data for predicting adverse human health effects associated with environmental contamination
- Developed special collection of manuscripts on the influence of gut microbiota on human dose-response relationships for salmonellosis published in *Human and Ecological Risk Assessment*

**ICF, International, Fairfax, VA (2010)**

- Provided expert consulting in medical microbiology and risk assessment, including problem formulation for land-applied biosolids
- Supported Department of Homeland Security in planning/evaluation of regional and national table-top exercises for biothreat preparedness (FEMA Anthrax Response Exercise Series)

**SRC, Inc., Environmental Science Center, North Syracuse, NY (2004 – 2009)**

- Served as technical project manager for EPA contracts (homeland security; waterborne pathogens; genetically modified organisms) and grants (microbial risk assessment; real time polymerase chain reaction detection of waterborne pathogens)
- Under EPA Microbial Risk Assessment CoE grant, principal technical support on: 1) peer review; 2) microbial risk assessment methodology; 3) microbial risk assessment of geospatial links between water quality monitoring, human infectious diseases in upstate NY counties
- Published peer-reviewed studies in *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*; *Foodborne Pathogens and Disease*; *Human and Ecological Risk Assessment*; *International Journal of Food Microbiology*; *Journal of Food Protection*; *Journal of Toxicology and Environmental Health*; *Microbe*; *Risk Analysis*; *Veterinary Microbiology*

**United States Department of Agriculture, Washington, DC, and other sites (1988 – 2004)**

- Supported risk assessments for microbial hazards in foods. Led *Campylobacter* risk assessment team, participated on teams for *Salmonella* and *E. coli* O157:H7 risk assessment projects
- Authored or co-authored 15 peer-reviewed studies on microbial risk in the following journals: *Applied and Environmental Microbiology*; *Food Control*; *Foodborne Pathogens and Disease*; *Human and Ecological Risk Assessment*; *International Journal of Food Microbiology*; *Journal of Association of Official Analytical Chemists*; *Journal of Food Protection*; *Journal of Toxicology and Environmental Health*; *Quantitative Microbiology*; *Risk Analysis*
- Served as expert reviewer for grants and projects of the Risk Assessment Consortium and Codex Committee on Food Hygiene
- Designed and conducted bridging experiments in predictive microbiology and modeling at Agricultural Research Service at Wyndmoor, PA and University of Maryland Eastern Shore

- Completed competitive Advanced Study in Microbial Risk Assessment at University of Georgia College of Veterinary Medicine, joined newly forming staff charged with developing, applying microbial risk assessment theory, methods, principles for regulatory support, decision-making
- Served as managing editor of a special collection of manuscripts on predictive microbiology and risk assessment published in *Risk Analysis*
- Served as US representative contributing to principles and guidelines document for microbial risk assessment approved by the international Codex Committee on Food Hygiene (1999)
- Conducted pilot studies for application of new technologies for detection and monitoring of pathogens in meat and poultry processing plants to support technology transfer

**Dynamac, International, Rockville, MD (1986 – 1988)**

- Assessed data for compliance with EPA guidance on pesticide re-registration in: product & residue chemistry, residue in animals/plants, environmental fate, occupational exposure

**Selected Publications and Reports**

- **2021.** Coleman, M.E., Dietert, R., North, D.W. Enhancing human superorganism ecosystem resilience by holistically ‘managing our microbes’. Invited manuscript for Special Collection (Human Microbiota Influence on Human Health Status), under review in *Applied Microbiology*
- **2021.** Coleman, M.E., North, D.W., Dietert, R., Stephenson, M. Examining evidence of benefits and risks for pasteurizing donor breastmilk. Invited manuscript under review in *Applied Microbiology*
- **2021.** Coleman, M.E. *Improving the Credibility of the Food Standards Australia New Zealand Report Entitled Microbiological Risk Assessment of Raw Cow Milk (2009) Considering New Evidence*. Report in preparation for Australian Raw Milk Movement, Incorporated
- **2020.** Coleman, M.E. *Technical Review of Food Safety Authority of Ireland (FSAI) Document Entitled ‘Advice on Shiga Toxin-Producing Escherichia coli (STEC) Detection in Food’*. Report prepared for Elizabeth Bradley, Carlow Farmhouse Cheese Company, Ireland
- **2018.** Coleman, M.E., C.A. Elkins, B.W. Gutting, et al. Microbiota and dose-response: Evolving paradigm of health triangle. *Risk Analysis* 38(10):2013-2028
- **2018.** McClellan, G.E., M.E. Coleman, D. Crary, et al. Human dose-response data for *Francisella tularensis* and a dose- and time-dependent mathematical model of early-phase fever associated with tularemia after inhalation exposure. *Risk Analysis* 38(8):1685-1700
- **2017.** Coleman, M.E., H.M. Marks, R.C. Hertzberg, et al. Mechanistic modeling of salmonellosis: Update, future directions. *Human & Ecological Risk Assessment* 23(8):1830-1856
- **2017.** Marks, H.M., M.E. Coleman. scientific data and theories for salmonellosis dose-response assessment. *Human and Ecological Risk Assessment: An International Journal*. 23(8):1857-1876
- **2017.** Coleman, M.E., H.M. Marks, T. Bartrand, et al. Modeling rabbit responses to single and multiple aerosol exposures of *Bacillus anthracis* spores. *Risk Analysis* 37(5):943-957
- **2012.** Peer review/beta testing for US FDA CFSAN iRISK tool
- **2011.** National Research Council. *Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL, Phase 3*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/13310>
- **2010.** Coleman, M.E. Reviews of *Food Safety Risk Analysis* and *Food-Borne Microbes: Shaping the Host Ecosystem*. Invited book reviews, *Risk Analysis* 30(5):866-871



- **2009.** Prepared invited review of US EPA framework for microbial risk assessment
- **2008.** Prepared invited review of USDA FSIS methodology for microbial risk assessment
- **2008.** Coleman, M.E., B. Thran, S.S. Morse, et al. Inhalation anthrax: Dose response and risk analysis. *Biosecurity Bioterrorism: Biodefense Strategy, Practice, and Science* 6(2): 147-160
- **2007.** Coleman, M.E., B. K. Hope, H.G. Claycamp, et al. *Microbial Risk Assessment Scenarios, Causality, and Uncertainty. Microbe* 2(1):13-17
- **2005.** Marks, H.M., and M.E. Coleman. Presenting scientific theories within risk assessment, *Human and Ecological Risk Assessment* 11(2):271-287
- **2005:** Marks, H.M., and M.E. Coleman. Accounting for inherent variability of growth in microbial risk assessment, *International Journal of Food Microbiology* 100(1-3):275-287
- **2005.** FSIS SE Risk Assessment Team. *Risk Assessments of Salmonella Enteritidis in Shell Eggs and Salmonella spp. in Egg Products*. Available at <https://tinyurl.com/y5x2mdrb>
- **2004.** Coleman, M.E., H.M. Marks, N.J. Golden. Discerning strain effects in microbial dose-response data, *Journal of Toxicology and Environmental Health* 67(8-10):667-685
- **2003.** Coleman, M.E., M. Tamplin, J. Phillips, et al. Influence of sub-optimal growth of the enteropathogen *Escherichia coli* O157:H7 on risk assessment, *International Journal of Food Microbiology* 83(2):147-160
- **2003.** Coleman, M.E. S. Sandberg, S. Anderson. Impact of microbial ecology of meat and poultry products on predictions from exposure assessment scenarios for refrigerated storage, *Risk Analysis* 23(1):215-228
- **2001.** USDA FSIS *Escherichia coli* O157:H7 Risk Assessment Team. *Risk Assessment of the Public Health Impact of Escherichia coli O157:H7 in Ground Beef*. Available at <https://www.fsis.usda.gov/wps/portal/fsis/topics/science/risk-assessments>
- **2000.** Coleman, M.E., H.M. Marks. Mechanistic modeling of salmonellosis, *Quantitative Microbiology* 2:227-247
- **1999.** *Principles and Guidelines for the Application of Microbiological Risk Assessment*. Codex Alimentarius Commission, Committee on Food Hygiene CAC/GL 30-1999
- **1999.** Coleman, M.E., H.M. Marks. Qualitative and quantitative risk assessment, *Food Control* 10(4-5):289-297
- **1998.** Marks, H.M., M.E. Coleman, C.-T. J. Lin, & T. Roberts. Topics in microbial risk assessment: Dynamic flow tree modeling, *Risk Analysis* 18(3):309-328
- **1998.** Coleman, M.E. & H.M. Marks. Topics in dose-response modeling, *Journal of Food Protection* 61(11):1550-1559
- **1998.** Marks, H.M. & M.E. Coleman. Estimating distributions of numbers of organisms in food products, *Journal of Food Protection* 61(11):1535-1540
- **1996.** Coleman, M.E., D.W. Dreesen, R.G. Wiegert. A simulation of microbial competition in the human intestinal tract, *Applied and Environmental Microbiology* 62(10):3632-3639
- **1983.** Chaplin, H., M.E. Coleman, M.C. Monroe. In vivo instability of red-blood-cell-bound C3d and C4d, *Blood* 62(5):965-971

## Key Presentations and Lectures

- **2021.** Accepted presentation on *Recent Evidence for Benefit-Risk Analysis of Raw and Pasteurized Milks* for 8<sup>th</sup> World Congress on Targeting Microbiota 2021 sponsored by the International Society of Microbiota
- **2021.** Invited webinar for Society for Risk Analysis entitled *Resilience and the Human Superorganism: Give Us this Day our Daily Microbes* (<https://www.sra.org/webinar/resilience-and-the-human-superorganism-give-us-this-day-our-daily-microbes/>)
- **2018 - 2021.** SUNY College of Environmental Science and Forestry, invited lecture, *Microbiome and Immunology: Interactions for Risk Assessors from 21<sup>st</sup> Century Science*
- **2020.** SRA virtual meeting, organizer, co-chair, technical symposium on *Data and Models for Dose-Response Relationships for SARS-CoV-2*, jointly sponsored by the SRA Dose-Response and Microbial Risk Analysis Specialty Groups, and co-author, *Human Data for Time- and Dose-Dependent Severity of COVID-19*
- **2020.** Webinar on *Recent Advances in Knowledge About the Microbiota of Milk and Butter* for Farm-to-Consumer Legal Defense Fund
- **2019.** SRA, Arlington, VA, co-author of presentation on *Evidence and Analysis Debunk Speculations about Raw Milk Risks*
- **2019.** 16<sup>th</sup> International Symposium on Milk Genomics conference, Copenhagen, Denmark. co-author of poster on *Producing Hygienic Raw Milk: Standards, Testing, and Farmer Education*
- **2018.** SRA, New Orleans, LA, organizer/presenter for round table panel symposium on *Communicating Evidence for Benefits and Risks of Raw Milks*
- **2017.** SRA webinar entitled *Preparing to Deliberate Evidence on Benefits and Risks Posed by the Microbiota of Milks* in series Advancing the Science: Microbiota Informing Benefits & Risks
- **2017.** Air and Waste Management Association/American Industrial Hygiene Association, Skaneateles, NY, invited lecture, *Evolution of Quantitative Microbial Risk Assessment (QMRA): Benefits of Low-Dose Exposures*
- **2014.** SRA, Denver, CO, presentation on *Exploring Disagreements Regarding Health Risks of Raw and Pasteurized Human and Bovine Milk*
- **2003.** 4th International Predictive Modeling Conference, Quimper, France, presentation on *Accounting for Inherent Variability of Growth in Microbial Risk Assessment*
- **2000.** Third International Conference on Predictive Microbiology in Foods, Leuven, Belgium, *Campylobacter, Salmonella, Listeria, and the Spoilage Flora: Who Wins the Battle?*
- **1997.** IAMFES/IAFP, Orlando, FL. Invited lectures on: *Risk Assessment/Risk Management: Clarifying the Relationships; Topics in Dose-Response Modeling; and Estimating Distributions of Numbers of Organisms in Food Products*
- **1996.** U.S./Japan Conference on Cholera and Diarrheal Diseases, Nagasaki, Japan. Invited lecture on *Microbial Risk Assessment*
- **1996.** SRA, New Orleans, LA, presentation on: *Topics in Microbial Risk Assessment*

**COMPLETE LIST OF PUBLICATIONS/ PRESENTATIONS AVAILABLE UPON REQUEST**

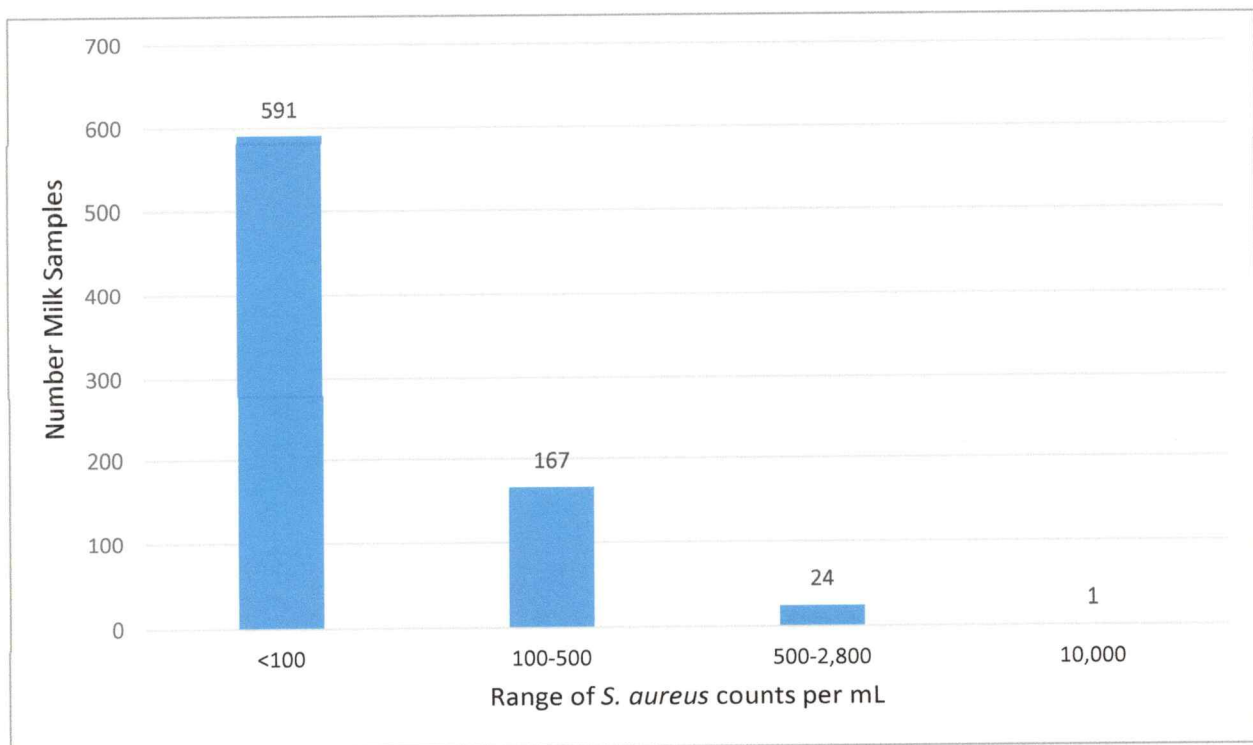


## APPENDIX 2. Results for *S. aureus* (NY, 2009 – 2014)

**Table A-2.1** Compliance Results for *S. aureus* in NY State Raw Milk (2009 – 2014)

| State | <i>S. aureus</i> Compliance<br>(# samples <10,000/mL/total #<br>samples, percentage compliant) | <i>S. aureus</i> NY State Standard<br>(mL) |
|-------|--|--|
| NY    | 782/783 (99.9%)  | 10,000                                     |

**Figure A-2.1** Results for *S. aureus* in NY State Raw Milk (2009 – 2014; maximum value 10,000)



### APPENDIX 3. Microbial Standards for Indicators and Major Pathogens in Raw and Pasteurized Cow Milk

**Table A-3.1** Some microbial standards for indicators and pathogens in raw and pasteurized milks

| Test  | Quality Standards<br>Raw Milk (NY)       | RAWMI Standards for<br>Listed Raw Milk Farms | Quality Standards<br>Pasteurized Milk<br>(PMO) |
|---|--|--|--|
| SPCs  | <30,000/mL                               | <5,000 SPCs/mL, rolling<br>3-month average   | <100,000 SPCs/mL                               |
| Coliform or<br>generic <i>E. coli</i>         | <i>E. coli</i> <10/mL<br>(recall if >10) | <10 coliforms/mL                             | <100 coliforms/mL                              |
| Major Pathogens                               | Zero<br>(recall if any)                  | Zero (divert if any)                         | Not required                                   |
| Opportunistic<br>pathogen<br><i>S. aureus</i> | <10,000/mL (recall<br>>100,000/mL)       | Not required                                 | Not required                                   |

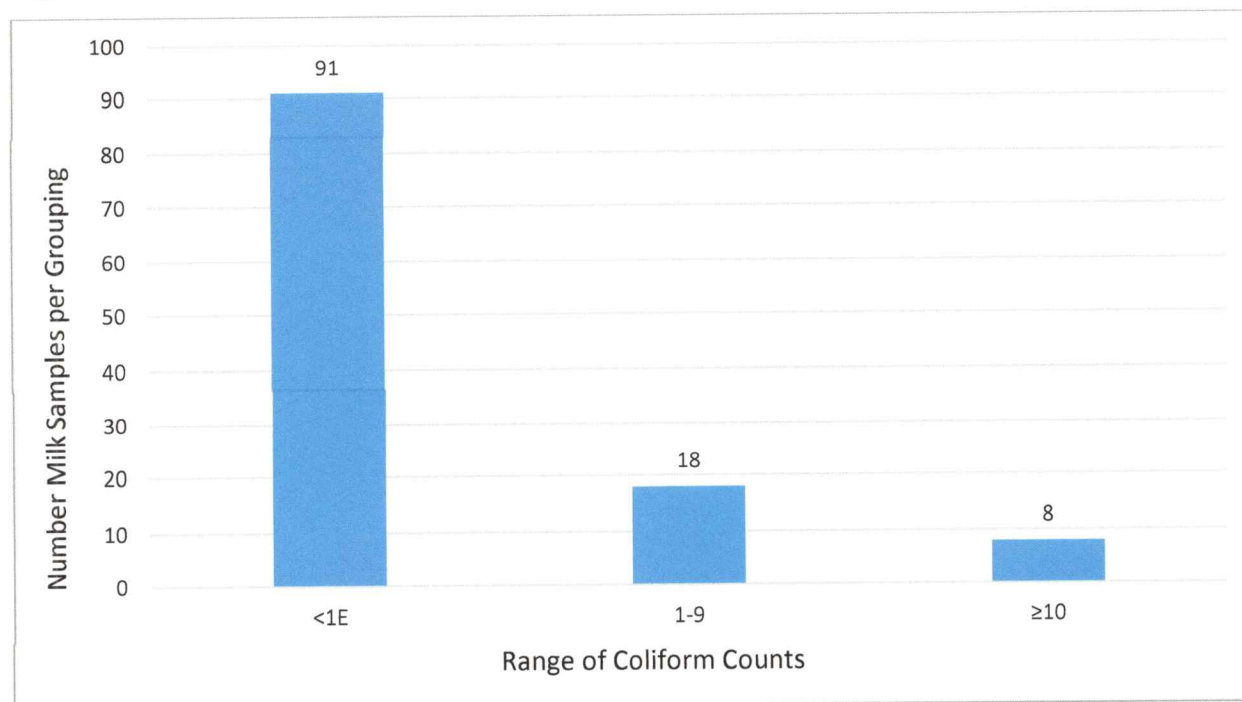


## APPENDIX 4. Results for Levels of Microbial Indicators in Raw Cow Milk from State Sampling Programs in Five Additional States

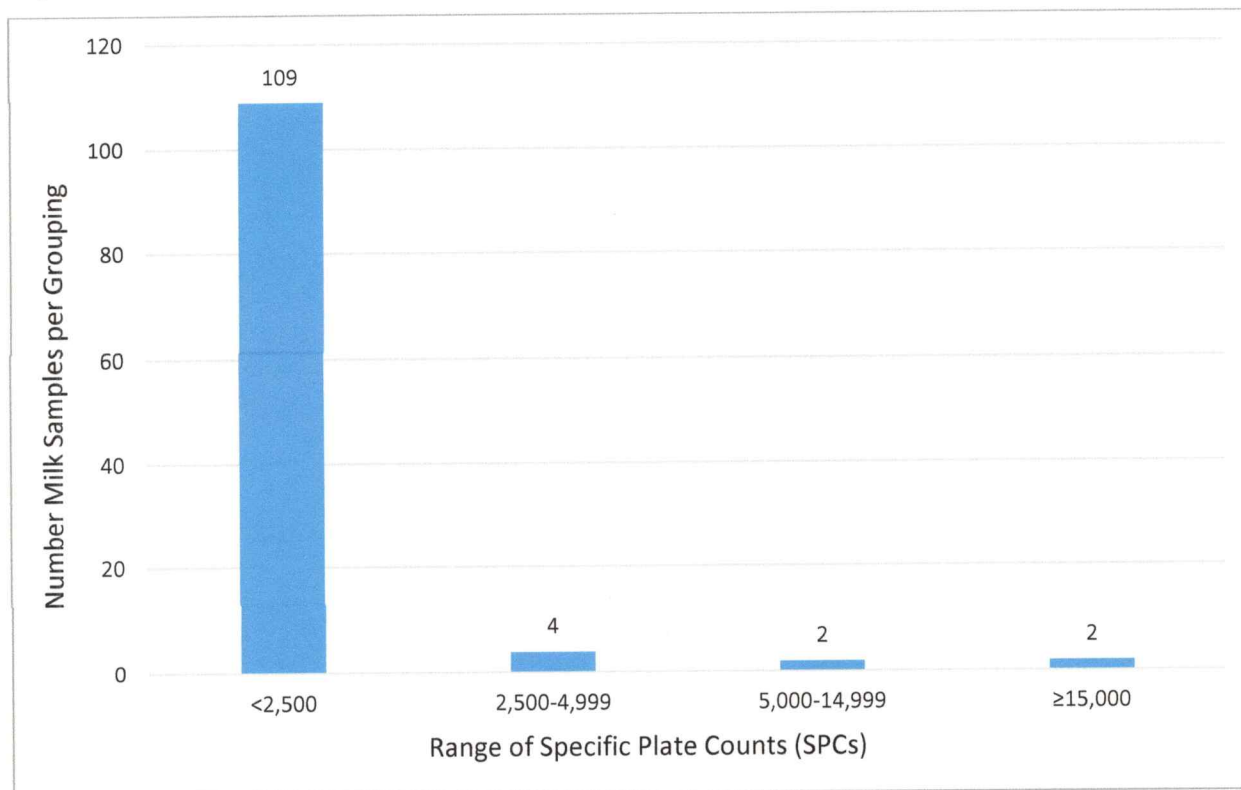
**Table A-4.1** Compliance Results for Microbial Indicators in Raw Milk by State

| State | Coliform Compliance<br>(# samples <10/mL/total #<br>samples, percentage<br>compliant) | SPC Compliance<br>(# samples <standard/total #<br>samples, percentage<br>compliant) | SPC Standards by<br>State (cfu/mL) |
|-------|---|---|------------------------------------|
| AZ    | 109/117 (93%)   | 116/117 (99%)   | 25,000                             |
| ID    | 967/1,130 (86%)   | 960/1,130 (85%)   | 15,000                             |
| MA    | 1,229/1,519 (81%)   | 1,027/1,115 (92%)   | 20,000                             |
| NH    | 262/382 (69%)   | 365/414 (88%)   | 20,000                             |
| SD    | 7/18 (39%)  | 26/30 (87%)   | 30,000                             |

**Figure A-4.1** Coliform results for AZ (2009 – 2014; maximum value 151)



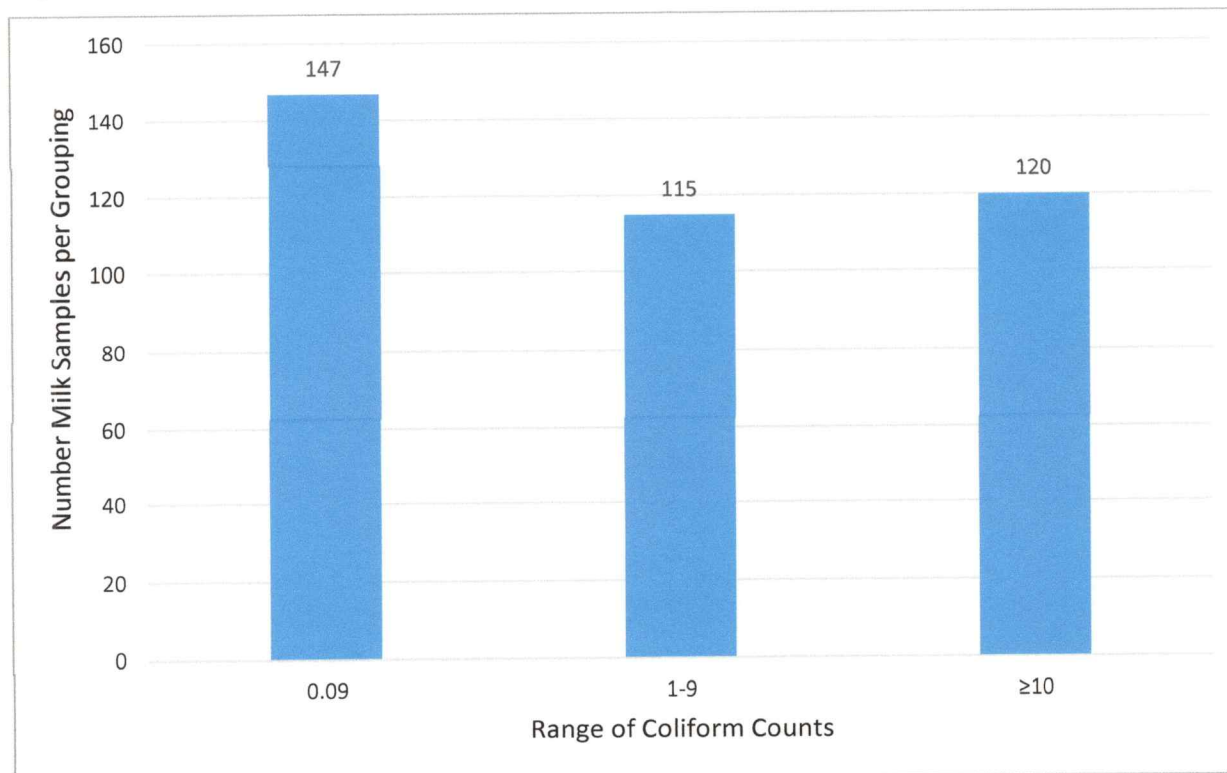
884 **Figure A-4.2** SPC results for AZ (2009 – 2014; maximum value 49,000)



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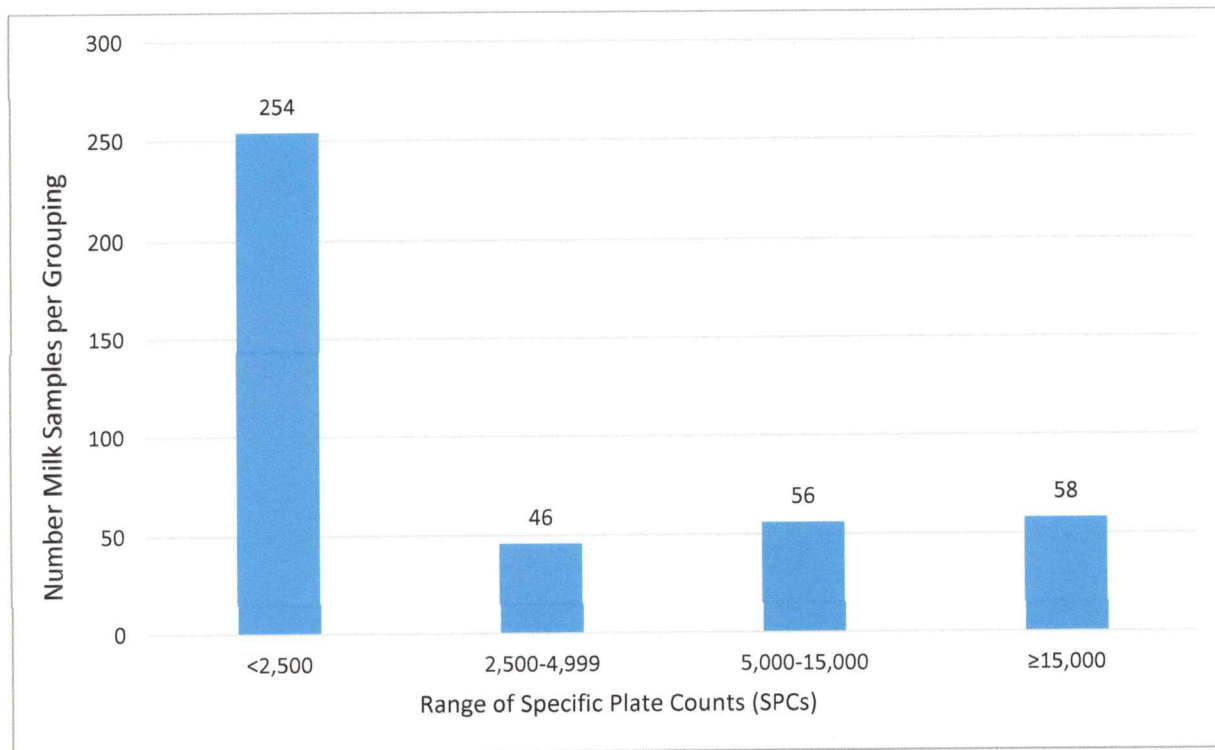
887 **Figure A-4.3** Coliform results for NH (2009 – 2014; maximum value; maximum value >250)



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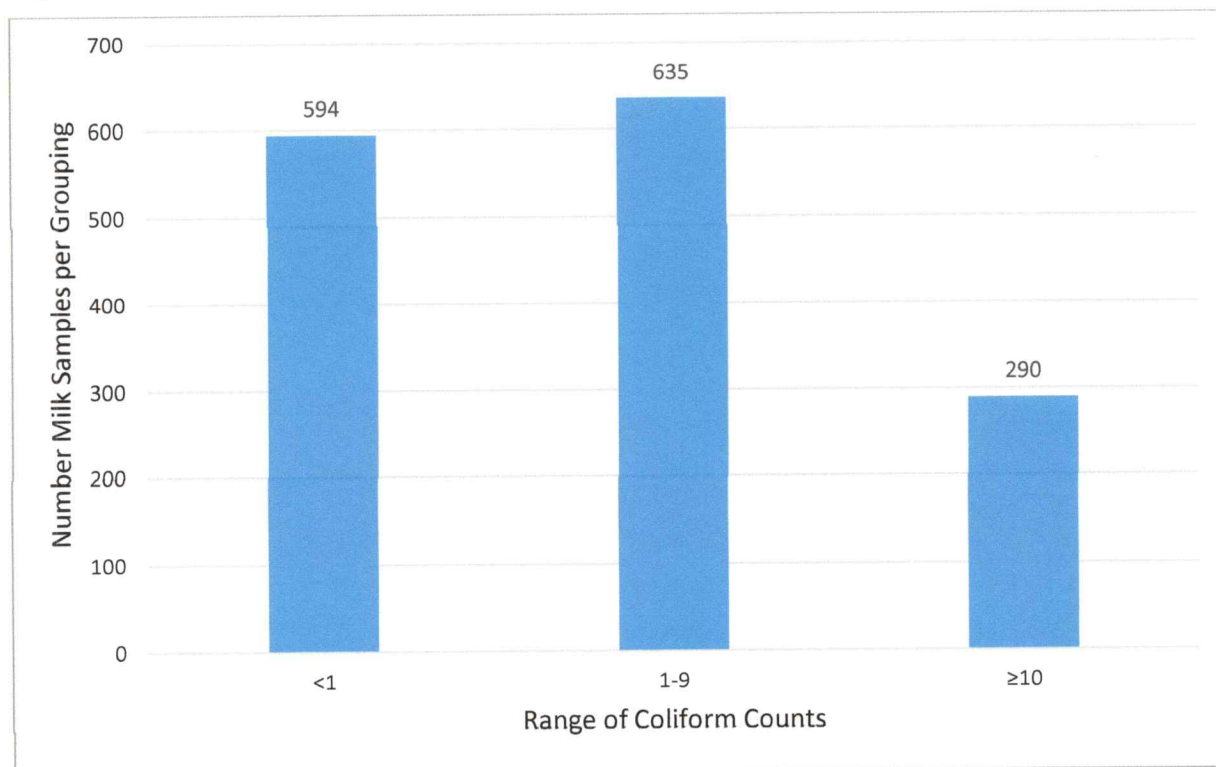
889 **Figure A-4.4** SPC results for NH (2009 – 2014)



890

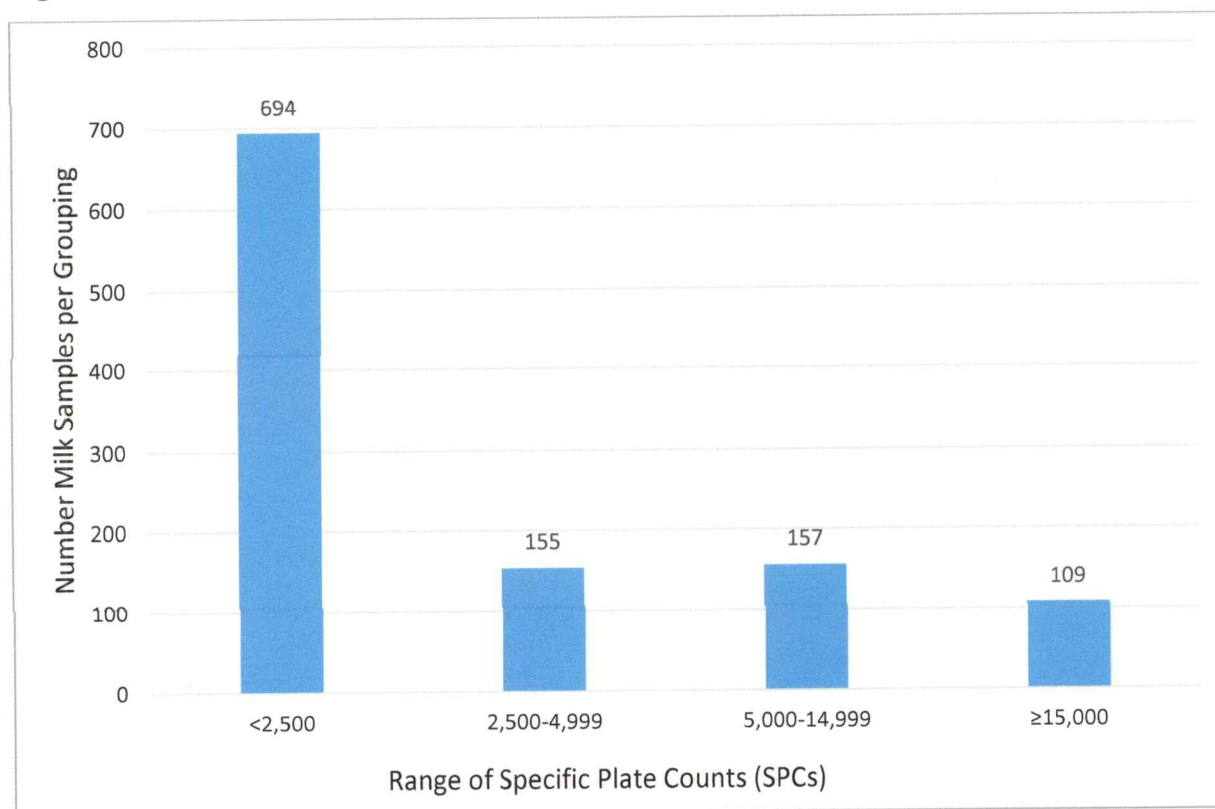
891

892 **Figure A-4.5** Coliform results for MA (2009 – 2014; maximum value; >150)



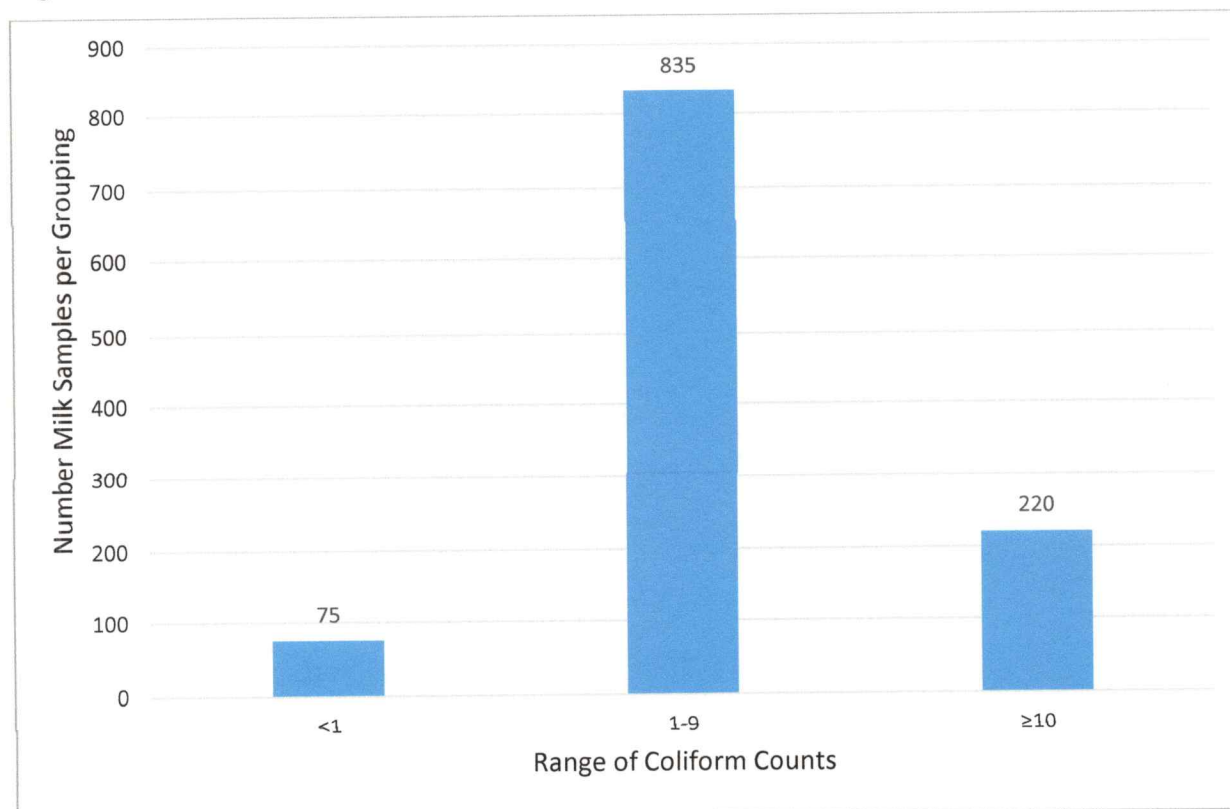
893

894 **Figure A-4.6** SPC results for MA (2009 – 2014; maximum value 4,000,000)



895

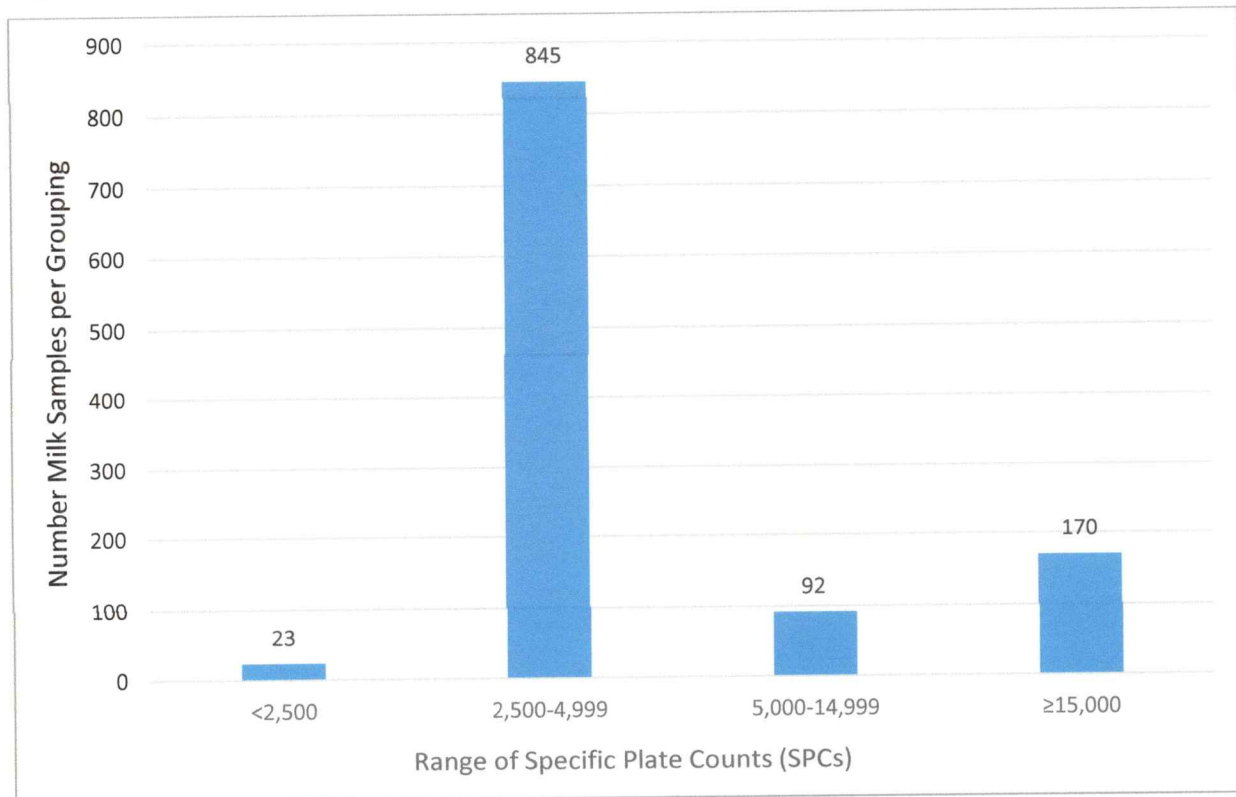
896 **Figure A-4.7** Coliform results for ID (2009 – 2014; maximum value 150)



897



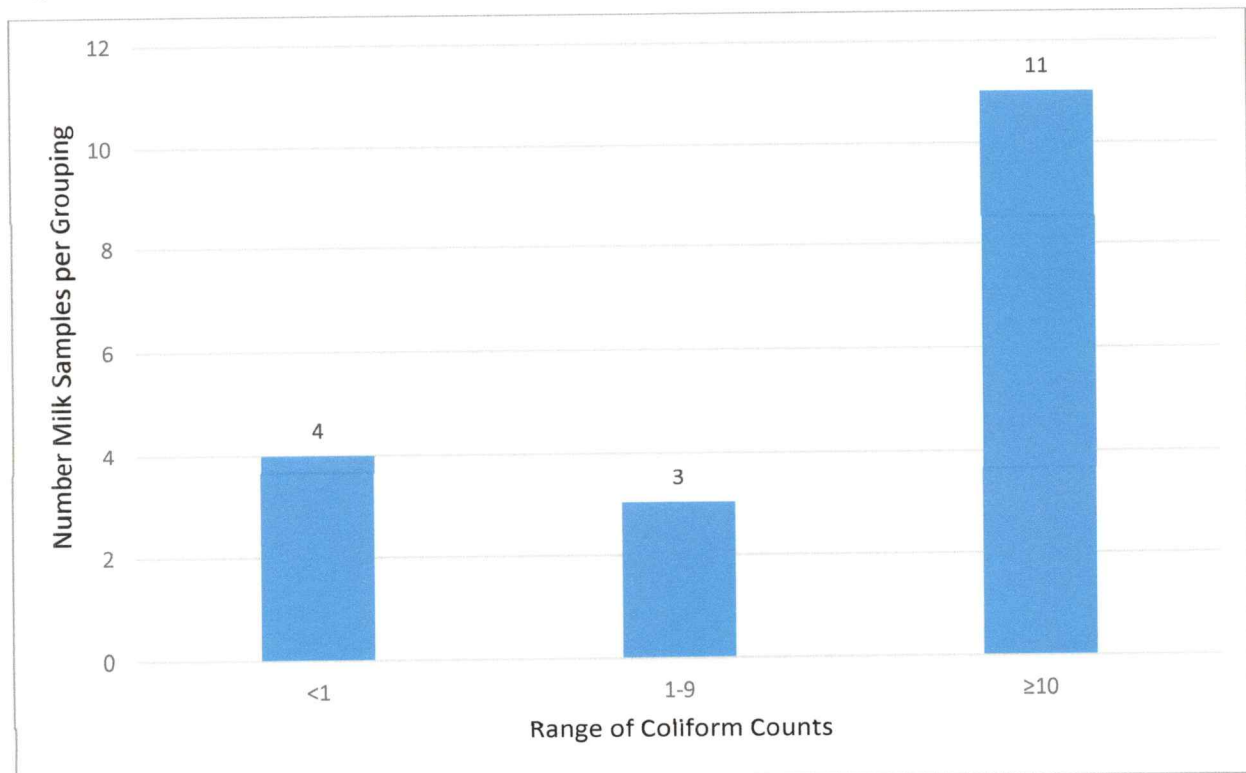
898 **Figure A-4.8** SPC results for ID (2009 – 2014; maximum value 2,000,000)



899

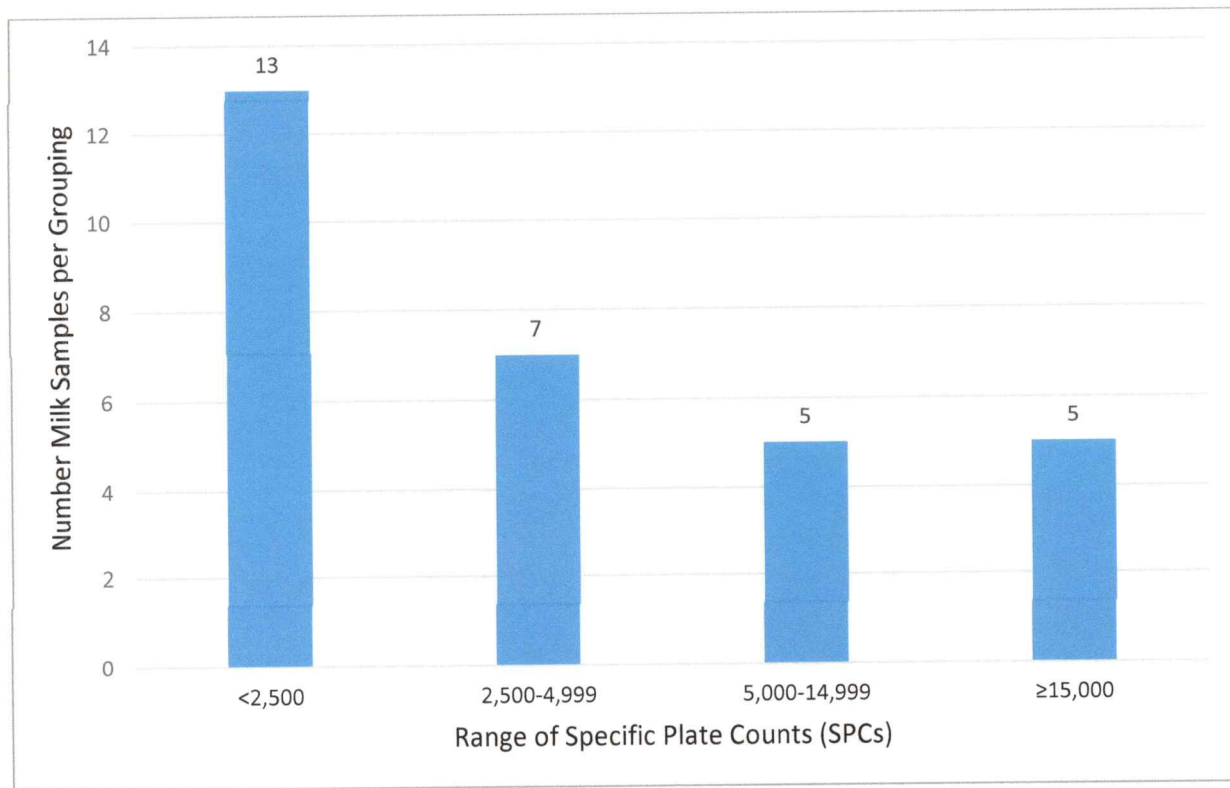
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901 **Figure A-4.9** Coliform results for SD (2009 – 2014; maximum value 800)



902

903 **Figure A-4.10** SPC results for SD (2009 – 2014; maximum value 510,000)



904

905



## APPENDIX 5. Summary of Data from Sources in Addition to FOIA Results from US State Programs

Recent prevalence data are available from raw milk sampling programs around the world (Table A-4.1). The table summarizes data from published studies and a Microsoft Access® database that includes data from US State monitoring (CA, NY, and WA, provided under the US Freedom of Information Act) and independent laboratories (provided by British Columbia Herdshare (as of February 2021) and Organic Pastures, Fresno, California). The certified laboratory MB Laboratories (Sidney, BC Canada) conducted analyses of raw milk for the 'BC Fresh Milk Project' of the British Columbia Herdshare Association (BCHA). Readers can review individual laboratory reports for each of 192 samples analyzed to date at <https://drive.google.com/drive/folders/0Bz2kJcZ3EjEleKVI1RmRhMmhBQzg>. Studies included in the table reflect raw milk for direct human consumption except pre-pasteurization milk noted by Marshall et al. (2016) and the second dataset from Berge and Baars (2020). The major pathogens were rarely detected in raw milk samples from multiple sources (generally undetected or <1% positive in the table below).

**Table A-5.1.** Recent Prevalence Data for Pathogens in Raw Milk from Samples Collected from 2009 to Present from Monitoring Programs Conducted around the World.

| Country<br>(Reference)  | Dates<br>(State if US)   | <i>Campylobacter</i>   | <i>E. coli</i><br>O157:H7 or<br>EHECs | <i>L.</i><br><i>monocytogenes</i> | <i>Salmonella</i> |
|---|--|--|---------------------------------------|-----------------------------------|-------------------|
| <b>Canada</b><br>(BCHA website<br>listed above)   | 2015-2021  | 0/192  | 0/192                                 | 0/192                             | 0/192             |
| <b>Poland</b><br>(Andrzejewska<br>et al., 2019)   | 2014-2018  | 0/113 vending<br>machines;<br>26/221 (12%)<br><i>C. jejuni</i> ,<br>directly from<br>farmers | Not Tested                            | Not Tested                        | Not Tested        |
| <b>UK</b><br>(McLauchlin et<br>al, 2020)  | 2017-2019  | 18/635<br>(2.8%)   | 0/58 O157;<br>3/304 EHEC<br>(0%, 1%)  | 1/642<br>(0.2%)                   | 3/622<br>(0.5%)   |
| <b>US State<br/>Monitoring</b><br>(database of<br>FOIA source<br>data from<br>licensed farms) | 2009-2014<br>(CA)  | 0/61   | 0/61                                  | 0/61                              | 0/61              |
|   | 2009-2014<br>(NY)  | 6/783<br>(0.7%)  | 0/782                                 | 1/781<br>(0.1%)                   | 0/780             |
|   | 2009-2014<br>(TX)  | 4/601<br>(0.7%)  | 0/596                                 | 4/596<br>(0.7%)                   | 11/606<br>(1.8%)  |
|   | 2012-2015<br>(WA)  | 0/497  | 0/502<br>2/501 (0.4%)                 | 0/502                             | 0/494             |
| <b>Germany</b><br>(Berge &<br>Baars, 2020)  | 2001-2015<br>(VZM)   | 7/2,352<br>(0.3%)  | 17/2,737<br>(0.7%)                    | 30/2,999<br>(1%)                  | 0/3,367           |
| <b>Germany</b><br>(Berge & Baars,<br>2020)  | 2001-2015<br>(not for direct<br>consumption<br>raw, pre-<br>pasteurized) | 17/2,258<br>(0.8%)   | 82/5,433<br>(1.5%)                    | 52/2,355<br>(2.2%)                | 0/1,084           |

| Country<br>(Reference)                        | Dates<br>(State if US)  | <i>Campylobacter</i>                       | <i>E. coli</i><br>O157:H7 or<br>EHECs   | <i>L.</i><br><i>monocytogenes</i>                            | <i>Salmonella</i>    |
|---|---|--|---|--|----------------------|
| <b>Finland</b><br>(Castro et al., 2017)       | 2013-2015   | Not Tested                                 | Not Tested  | 5/105 retail bottles<br>(4.8%)<br>2/115 bulk tanks<br>(1.7%) | Not Tested           |
| <b>Finland</b><br>(Jaakkonen et al., 2019)    | 2014-2015   | 0/789                                      | 0/789<br>O157:H7;<br>2/789<br>O121:H19<br>(<1%)   | Not Tested   | Not Tested           |
| <b>US</b><br>(Del Collo et al., 2017)         | 2014<br>(17 states)   | 13/234 culture;<br>27/234 PCR<br>(6%; 12%) | Not Tested  | Not Tested   | Not Tested           |
| <b>Italy</b><br>(Trevisani et al., 2013)      | Unspecified<br>(prior to 2013;<br>not for direct<br>consumption<br>raw, dairy<br>silos) | Not Tested                                 | 34/200 (17%)<br>PCR;<br>12/34 (35%)<br>culture;<br>27/34 (79%)<br>viable RT-<br>PCR;<br>1/40 batches<br>PCR EHEC<br>virulence genes | Not Tested   | Not Tested           |
| <b>New Zealand</b><br>(Marshall et al., 2016) | 2011-2012,<br>(not for direct<br>consumption<br>raw, pre-<br>pasteurized)               | 2/400<br>(0.6%)                            | 2/400<br>(0.6%)   | 16/400<br>(4.0%)   | 0/400                |
| <b>Italy</b><br>(Bianchini et al., 2014)      | 2010-2012<br>(pre-<br>pasteurization)   | 34/282<br>(12%)                            | Not Tested  | Not Tested   | Not Tested           |
| <b>Finland</b><br>(Ricchi et al., 2019)       | 2011  | Not Tested                                 | Not Tested  | 1/120 milk samples<br>from individual<br>cows positive       | Not Tested           |
| <b>Italy</b><br>(Giacometti et al., 2013)     | 2008-2011<br>(official<br>sampling<br>licensed raw<br>milk farm<br>vending<br>machines) | 53/60,907<br>(<2.2%)                       | 24/60,907<br>(<1.5%)  | 83/60,907<br>(<1.6%)   | 18/60,907<br>(<1%)   |
| <b>Italy</b><br>(Giacometti et al., 2012)     | 2010<br>(official<br>sampling<br>licensed raw<br>milk farm<br>vending<br>machines)      | 0/99<br>(ISO, 1 PCR,<br>BAM)               | 0/99<br>(ISO; 1 BAM)  | 0/99<br>(ISO; 1 PCR)   | 0/99<br>(ISO, 1 BAM) |



| Country<br>(Reference)          | Dates<br>(State if US)  | <i>Campylobacter</i> | <i>E. coli</i><br>O157:H7 or<br>EHECs | <i>L.</i><br><i>monocytogenes</i> | <i>Salmonella</i>                  |
|---------------------------------|---|----------------------|---------------------------------------|-----------------------------------|------------------------------------|
| US<br>Jackson et al.,<br>(2012) | 2009-2010<br>(not for direct<br>consumption<br>raw,<br>regionally<br>representative<br>dairy silos) | Not Tested           | 4/184<br>(2%)                         | 107/214<br>(50%)                  | (45-124)/(211-<br>214)<br>(21-58%) |

## 921 Highlights of Jaakkonen Study

922 The study by Jaakkonen and colleagues (2019) cited in table above is relevant to this project because the  
 923 authors report relevant data on pathogens from a longitudinal study sampling raw milk, feces, drinking  
 924 troughs, and milk filter from three Finnish dairy farms over time.

925 Results for EHECs differed by culture-dependent and culture independent methods. Zero raw milk of 789  
 926 samples were culture-positive for *E. coli* O157:H7, and two of 789 were culture-positive for non-O157  
 927 STECs, both serotype O121:H19). Despite 0% and <1% culture positives for STECs, PCR testing for  
 928 virulence genes alone yielded 52/789 (7%) raw milk samples positive for the Shiga toxin gene and 32/789  
 929 (4%) positive for both the Shiga toxin gene and the *eae* gene (associated with the capability for STECs to  
 930 form attaching and effacing lesions), necessary but not sufficient for infectivity and virulence.

931 Jaakkonen reported zero raw milk samples among 785 that tested positive for *C. jejuni* (see Table A-5.1)  
 932 although feces of milking cows (115/164, 70%), juvenile cows (21/93, 23%), drinking troughs (10/199,  
 933 5%), and milk filters (1/631, <1%) were positive (see Table A-5.2).

934 However, the authors of this study offered ‘conclusions’ that raw milk must be pasteurized to prevent  
 935 infections and that milk filters should be used for pathogen testing rather than milk when neither  
 936 ‘conclusion’ is supported by data or statistical analysis. Evidence from independent experts cited herein  
 937 clarifies that these statements by the authors are speculations or presumptions, not conclusions based on  
 938 definitive scientific evidence and analysis.

939 Further, the authors made many claims that were not supported by scientific evidence, including the  
 940 following.

- 941 1) ‘Health risks of raw milk can effectively be avoided only by heat treatment (pasteurization) of  
 942 the milk before consumption’.
- 943 2) ‘Milk filters are more suitable targets for monitoring than milk because Shiga toxins genes are  
 944 detected at higher prevalence on filters’.
- 945 3) ‘Only a few cells of STECs and *Campylobacter jejuni* may cause serious public health effects’.
- 946 4) ‘One glass (200 mL) of milk could cause infection with the contamination levels observed in  
 947 this study’.

Jaakkonen and colleagues appear to be unaware of crucial bodies of evidence that undermine their claims, including an earlier longitudinal study (Lambertini et al., 2015) that demonstrated that although Shiga toxins can be nearly ubiquitous in dairy environments, no significant correlation was observed between fecal positives and milk filter positives, and neither feces nor milk filters were predictive of milk positives. Additional studies that refute the claims of the authors are noted below.

1. No evidence is presented or cited that demonstrates statistical significance for milk filters as predictors of risk of illness for people consuming milk.
2. The presence of a toxin in feces, filters, or raw food is insufficient to predict risk without supplemental data about levels of a viable pathogen consumed, expression of multiple virulence genes, and observation of illness or application of a dose-response model that incorporates variability and uncertainty for the disease triad (host, pathogen, and environment).
3. The authors appeared to test raw milk intended for pasteurization, since they considered sampled raw milk to be of "good hygienic quality" when it had bacterial test results 'usually below 50,000 standard plate count (SPC) per milliliter'.
4. The authors do not describe the 'national policies and rigorous hygienic measures' implemented by the 3 farms with a history of pathogen positives that they chose to sample. It is unlikely that these 3 farms are representative of all licensed raw milk dairies.
5. Raw milk producers that follow stringent practices and procedures, including HACCP and regular testing for standard plate counts (SPC), coliforms and pathogens, consistently meet higher standards of hygiene ( $\leq 5,000$  SPC/mL (typically  $< 500$  SPC/mL) and  $\leq 10$  coliforms/mL; <https://www.rawmilk institute.org/listed-farmers>) and caused rare illnesses and no deaths in recent decades.
6. Pasteurized milk recently caused 4 deaths in Canada (Hanson et al., 2019), and ice cream from pasteurized milk caused 4 more deaths in the US (Pouillot et al., 2016). Pasteurization does not eliminate risk of illness or death.
7. The paper does not cite the best available scientific data and methods for assessing risk and effectiveness of risk management strategies for raw milk, including HACCP and pasteurization, nor a recent quantitative microbial risk assessment (Giacometti et al., 2017) that acknowledge that their current and previous models applied assumptions that oversimplified the complexity of risk assessment for raw milk and likely overestimated risk of campylobacteriosis, listeriosis, salmonellosis, and STEC illnesses and HUS cases associated with raw milk. Low levels of exposure to *E. coli* O157:H7 ( $< 0.4$  MPN/mL) and low numbers of severe illnesses (7 reported HUS cases in 7 years) were consistent with 99% of the population consuming milk raw, without boiling, even though regulators recommended boiling.
8. The authors cited Mungai et al. (2015) who speculated that increased access to raw milk in the US will increase outbreaks and illnesses, not the more recent study of Whitehead and Lake (2018) disproving this speculation.
9. The authors did not measure or report contamination levels for pathogens in their study, or conduct a valid microbial risk assessment for infection or illness from contaminated servings, or



- 987 monitor reported illnesses attributed to consumers of raw milk from the 3 farms sampled during  
988 the period of the study.
- 989 10. The authors cite one study characterizing the dense and diverse natural microbiota of raw milk  
990 (Quigley et al., 2013), but fail to apply basic microbial ecology concepts and principles to their  
991 speculations about exposure and risk (Coleman et al., 2003a,b).
- 992 11. Extensive data on mechanisms of protection of food microbiota against growth/survival of  
993 pathogens and stimulation of innate and adaptive immunity is not even acknowledged by the  
994 authors. They ignore documented microbial stimulation of innate defenses, particularly  
995 'colonization resistance' of the dense and diverse healthy human microbiota that excludes or  
996 protects against pathogens and disrupts pathogenesis, whereas less diverse microbiota are less  
997 effective in suppressing pathogen growth and reducing progression to illness, even in susceptible  
998 populations (Stein et al., 2013; Buffie et al., 2015; Dietert, 2017a,b; Dietert, 2018; Sorbara and  
999 Pamer, 2019).
- 1000 12. The authors have not considered the ecological systems of the milk microbiota or the gut  
1001 microbiota that influence dose-response assessment and risk analysis. Less virulent or avirulent  
1002 species related to the pathogens or commensals causing no demonstrated adverse effects  
1003 protected against progression of illness through colonization resistance, despite likely exposure  
1004 (Stein et al., 2013; Buffie et al., 2015; Sorbara and Pamer, 2019).
- 1005 13. The authors introduce data from genomic methods and speculate about risks, but do not cite three  
1006 recent studies (Pielaat et al., 2015; Kiel et al., 2018; Njage et al., 2018) that incorporated genomic  
1007 data into microbial risk assessments for better predicting illness. All three note that presence of a  
1008 pathogen or its toxins in food is not predictive of infection or illness.
- 1009 14. No data is presented or cited for assessing the dose-response relationships for O157:H7, the other  
1010 STEC detected (O121:H19), or *Campylobacter jejuni*. Nor are extensive data on suppression of  
1011 growth from low densities at refrigeration temperatures (Coleman et al., 2003a,b) and from the  
1012 competing milk microbiota for estimating risk, though they acknowledge raw milk has a 'rich  
1013 competing microbiota'.
- 1014 15. FAO/WHO (2019) notes that 'infectious doses' for STECS (doses causing illness) are  
1015 SUSPECTED to be low, perhaps <100 for some strains. However, they note that the actual  
1016 scientific evidence for 'low infectious doses' of *E. coli* O157:H7 is weak, based on indirect  
1017 evidence from companion samples of foods from contaminated lots associated with outbreaks. No  
1018 dose-response data are available for more than 400 less virulent STEC serotypes including the  
1019 only serotype detected in 2/789 milk samples in this study, *E. coli* O121:H19.
- 1020 16. Stronger evidence is not cited from human volunteers who demonstrate innate and adaptive  
1021 immunity to high doses of virulent *Campylobacter* strains from two studies, including a recent  
1022 US Army study (Tribble et al., 2010) that demonstrated resistance to 1,000,000,000 pathogen  
1023 cells. The authors do not acknowledge uncertainties for dose-response models and risk estimates,  
1024 whether based on evidence from outbreak investigations or human volunteer studies (Monge et  
1025 al., 2016).

17. Frequent exposures of poultry abattoir workers to *Campylobacter* generally caused no illness, or asymptomatic infection, but resistance to infection linked to gut microbiota composition of the workers (Dicksved et al., 2014).
18. A healthy innate immune system can protect against low doses of many pathogens. In fact, healthy immune systems may REQUIRE exposure to bacteria including low doses of pathogens for balanced functioning (Dietert, 2018). A study of human travelers demonstrated lower gut microbiome diversity for travelers who became ill compared to those likely exposed but resistant to infection (Kampmann et al., 2016).
19. Evidence from a large study including 1,559 people showed that *Campylobacter* exposures ‘vastly exceed’ clinical illness based on antibodies directed against this pathogen in human blood (Monge et al., 2018).

**Table A-5.2.** Results for microbial sampling in raw milk, milk filters, and feces reported by Jaakkonen et al (2019)

| Pathogen or Virulence Gene                  | Milk             | Milk Filter               | Feces      |
|---|------------------|---------------------------|------------|
| <i>Campylobacter</i>                        | 0/785            | 1/631                     | 136/257    |
| O157:H7                                     | 0/789            | 12/632                    | 44/247     |
| Other STECs                                 | 2/789 (O121:H19) | 6/632 (O182:H25; O26:H11) | Not tested |
| <b>STEC Virulence Gene Screening by PCR</b> |                  |                           |            |
| <i>stx</i> gene                             | 52/789           | 233/631                   | Not tested |
| <i>stx</i> and <i>eae</i> genes             | 32/789           | 178/631                   | Not tested |

In summary, although the Jaakkonen study (2019) reports some data relevant to issues concerning raw milk quality and safety, the ‘conclusions’ that they offered are invalid and unsupported. The ‘conclusions’ grossly overreach the data generated and the methodology applied. The authors appear to exclude or overlook studies that provide more definitive data that conflict with their assumptions and ‘conclusions’. Thus, it seems that the authors imposed significant bias and overconfidence in their interpretation of ‘the limited dataset used in our study’ despite noting that ‘results can be regarded as preliminary and should be verified with more data’. Other evidence from independent experts referenced herein illuminates that the authors’ ‘conclusions’ are actually speculations or presumptions, not valid conclusions based on definitive scientific evidence generated by the study as designed and tested by objective statistical methods. Neither did the authors apply appropriate microbial risk analysis methodology to test hypotheses regarding risk of human infection or illness in consumers of raw milk produced during the pilot study.

From the perspective of microbial risk assessment, the Jaakkonen study (2019) does not demonstrate that any of the potential factors included in the study design (feces, drinking troughs, and milk filters) are predictive of prevalence of pathogens in raw milk using valid statistical methods. Neither are PCR tests for Shiga toxin genes or the combination of Shiga toxin and *eae* genes predictive of the prevalence of



viable EHEC/STECs in raw milk. No data on levels of pathogens present in raw milk or other matrices was provided, preventing any assessment of risk with attendant uncertainty by any valid QMRA methodologies. The presence/absence data for pathogens or genes potentially encoding toxins generated by these researchers are insufficient for assessing risk or risk reductions of potential interventions.

Thus, the data reported in the Jaakkonen study appears to falsify the common but incorrect assumptions that 1) fecal positives are predictive of milk positives; and 2) filter positives are predictive of milk positives.

### Highlights of Test-and-Hold Program

In addition, data were provided from a Test-and-Hold Program in the US. Results on pathogens in raw milk were provided by the independent certified laboratory, Food Safety Net Services (FSNS, Fresno, CA USA) for a U.S. Test-and-Hold Program at a raw milk producer for 2018-2020 (Organic Pastures, Fresno, CA; McAfee, 2021). Regular testing is in use for the pathogen *E. coli* O157:H7/EHECs using rapid methods (polymerase chain reaction or PCR, results available within 18 hours of sampling).

In 898 raw milk samples analyzed by the independent laboratory in June 2018 to December 2020, none tested positive or was diverted from sale as raw milk. The enrichment methods and PCR technology for other pathogens required longer times for analysis and confirmation by the same independent laboratory, and testing is conducted less frequently. In 109 raw milk samples analyzed for *Listeria monocytogenes* and *Salmonella* spp., none tested positive or was diverted from sale as raw milk. For *Campylobacter* spp., 15 positives and 2 presumptives of 123 raw milk samples were detected and diverted from direct retail sale to consumers (sold to pasteurizers). Additional screening of environmental samples was conducted for *L. monocytogenes*, and serial screening of composite raw milk samples was conducted for *Campylobacter* in response to presumptive results to identify positive animals and remove them from the herd or divert their milk from direct sale as raw milk at retail.

Regular testing was conducted for the pathogen *E. coli* O157:H7/EHECs using rapid methods (enrichment, culture, and confirmation by polymerase chain reaction or PCR, results available within 18 hours of sampling). In 898 raw milk samples analyzed by an independent laboratory in 2018 to 2020, none tested positive or was diverted from sale as raw milk. The rapid testing methodology for other pathogens (enrichment, culture, and PCR confirmation) required longer times for analysis and confirmation by the same independent laboratory, and testing is less frequent. In 109 raw milk samples analyzed for the pathogen *Listeria monocytogenes* and the genus *Salmonella*, none tested positive or was diverted from sale as raw milk. For the genus *Campylobacter*, 15 positives and 2 presumptives of 123 raw milk samples were detected and diverted from sale to consumers. Additional screening of environmental samples was conducted for *L. monocytogenes*, and serial screening of composite raw milk samples was conducted for *Campylobacter* in response to presumptive results to identify positive animals.

Note that the Test-and-Hold data are NOT appropriate for estimating human exposure or risk because the enrichment step imposes a bias for higher detection, particularly for *Campylobacter* spp. that do not grow in raw milk at refrigerated temperatures or in competition with the natural microbiota. The US regulatory agency that conducts regular microbial testing for these four pathogens records only direct plating results (FSIS, 2014). Further, the rapid test methods identify *Campylobacter* and *Salmonella* only to genus, and characterization of pathogenicity and virulence of isolates would be needed for use in risk assessment. Even for the pathogen *L. monocytogenes*, high variability between strains in pathogenicity and virulence noted in multiple studies (FDA/FSIS, 2003; Chen et al., 2003, 2006; Bertrand et al., 2016; Stout et al.,

1097 2019) point to the need for incorporating additional evidence in QMRAs for Dose-Response Assessment,  
1098 rather than applying another worst-case assumption that all strains in raw foods have infectivity and  
1099 virulence equal to outbreak strains. Also, any positive lot from the Test-and-Hold Program is diverted  
1100 from sale to consumers, reducing the public health risk further by preventing human exposures to lots that  
1101 may contain viable and infectious microbes that could, at sufficient dose, have caused human illnesses  
1102 among consumers.

1103 Certainly, because *Campylobacter* is sampled less frequently compared to STECs (123 samples vs 898  
1104 over the 3-year period), it is possible that a percentage of retail raw milk samples screened for STECs but  
1105 not for *Campylobacter* could be positive and result in exposure to California raw milk consumers. It is  
1106 possible that if the screened 123 samples (17 positive of 123, 13.8%) were representative of other lots of  
1107 raw milk that were not screened for *Campylobacter*, the rate of *Campylobacter* positives in unscreened  
1108 lots could be 13.8%. However, no campylobacter cases associated with raw milk were reported in this  
1109 time-period in the state. Thus, these data falsify the common assumption that presence of pathogens in  
1110 raw milk renders it inherently dangerous.

1111 Notably, the outdated assumption that test-and-hold programs are untenable for raw milk producers has  
1112 also been proven false due to significant technological advances in molecular and genetic rapid testing  
1113 methodologies achieved in the past decade.

1114 To put the test-and-hold program data in perspective as to public health, no outbreaks were reported in the  
1115 state (CA) for this period for any pathogens (including all four major pathogens), to our knowledge.  
1116 Regarding data from the Centers for Disease Control and Prevention (CDC), National Outbreak Reporting  
1117 System (NORS) data on US dairy outbreaks, a dataset for 2005-2017 has already been received and  
1118 analyzed for other projects, and data for 2018 and 2019 was received recently. Data for 2020 is not  
1119 available from CDC at present, though no raw milk outbreak reports for CA in 2020 were identified in  
1120 literature searches. From CDC NORS data, two campylobacteriosis outbreaks were reported in the state  
1121 of CA in the prior decade, one in 2015 that sickened 8 people and one in 2012 that sickened 33. The only  
1122 other outbreak reported in the state in the past decade was for *E. coli* O157:H7/EHECs that sickened 5  
1123 people in 2011, none of whom developed the severe complication of hemolytic uremic syndrome or HUS.  
1124 No deaths were attributed to raw milk in the state in more than a decade. Over the 3-year period of the  
1125 Test-and-Hold Program (2018-2020), Organic Pastures produced 4,280,922 gallons of raw milk, of which  
1126 1,351,684 gallons (31.5%) was bottled for direct human consumption at retail in California (McAfee,  
1127 2021, personal communication).

1128 Since no raw milk outbreaks associated with microbial pathogens were reported in California in this  
1129 period, estimates based on available recent data combined with the consumption estimates for children  
1130 and adults cited in the FSANZ report (2009) are that risk of illness is less than 1 in 9.5 million servings  
1131 for children and less than 1 in 12.9 million servings in adults for consumers in California who choose to  
1132 buy Organic Pastures raw milk at retail markets.

1133 Thus, recent data for Exposure Assessment do not support the outdated assumptions that raw milk is  
1134 inherently dangerous and that existing hygienic management programs, including HACCP and Test-and-  
1135 Hold Programs, cannot ensure a safe, low-risk product for raw milk consumers.