Quantitative Assessment of the Risk of Listeriosis from Soft-ripened Cheese Consumption in the United States and Canada.

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Background

- The United States and Canada continue to experience sporadic illness and outbreaks of listeriosis associated with the consumption of cheese
- FDA and Health Canada (HC) continue to evaluate the safety of cheese, particularly cheese made from unpasteurized milk

➢ FDA and HC carried out a QMRA to evaluate the effectiveness of and the public health impact of processing and intervention strategies to reduce or prevent *Listeria monocytogenes* in soft-ripened cheeses.

Scope

- **Pathogen:** *Listeria monocytogenes*
- **Food:** Camembert, as an example of soft-ripened cheese
- **Population of Interest:**
  - General population of the U.S. and Canada
  - Subpopulations identified as at-risk in both countries
- **Endpoint:** Invasive listeriosis
- (primary) **Risk metric:** Probability of invasive listeriosis per soft-ripened cheese serving

- **Baseline**
  - "Pasteurized-milk cheese",
    i.e. Soft-ripened cheese made from pasteurized milk, "stabilized process"

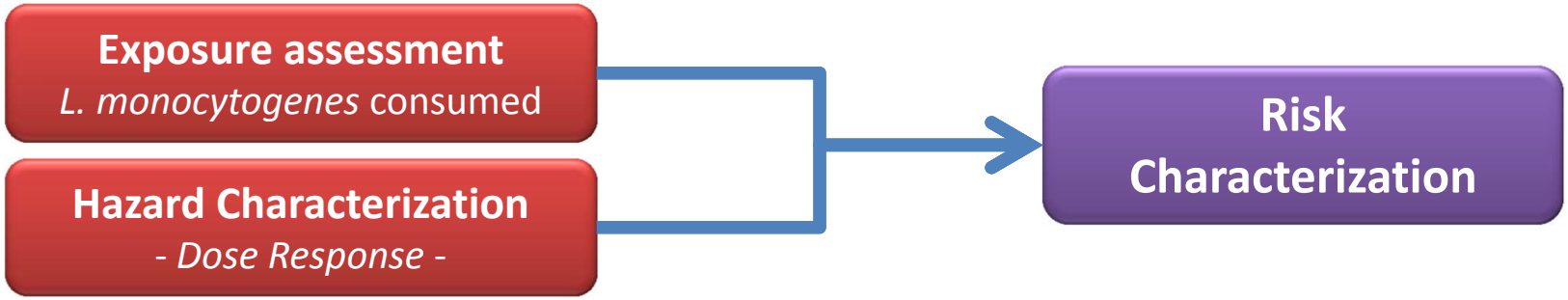
Vs.

- **Alternatives**
  - "Raw-milk cheese",
    i.e. Soft-ripened cheese made from raw milk, "traditional process", Farmstead scale

  - "Raw-milk cheese" or
    "Pasteurized-milk cheese" according to various mitigation strategies

Framework / Model / Data

- Framework: *Codex Alimentarius*, FDA, HC

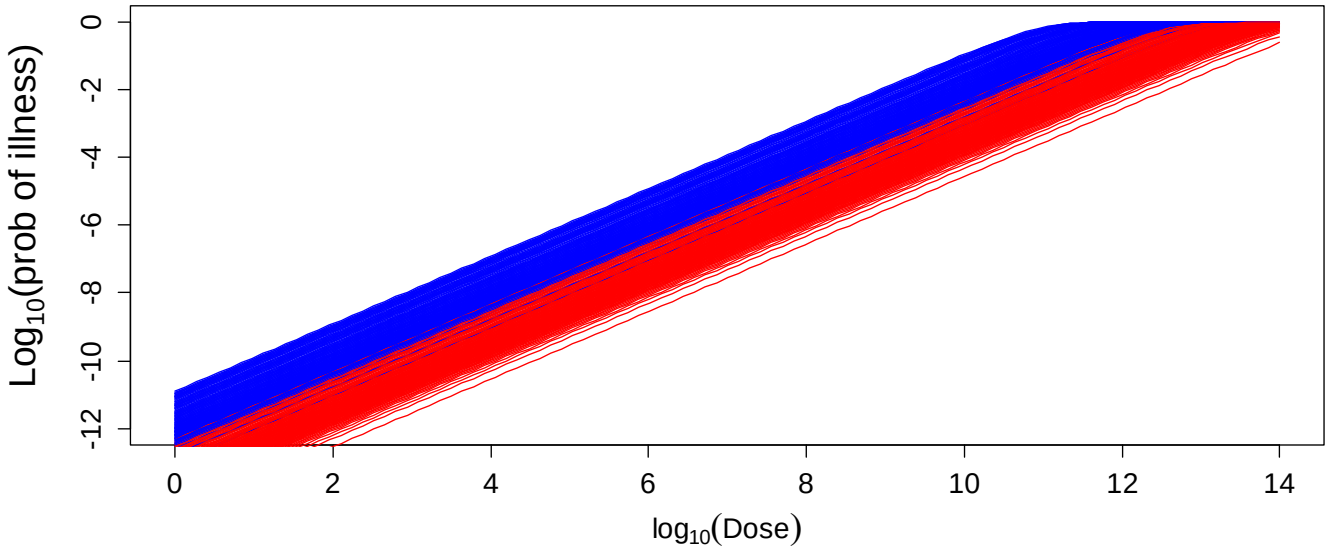


- Fully quantitative risk assessment
  - Second-order Monte Carlo simulation
- Model structure based on
  - Literature, Previous risk assessments, Expert sources
- Data based on
  - Literature, Government surveys, Specific expert elicitations

Hazard Characterization

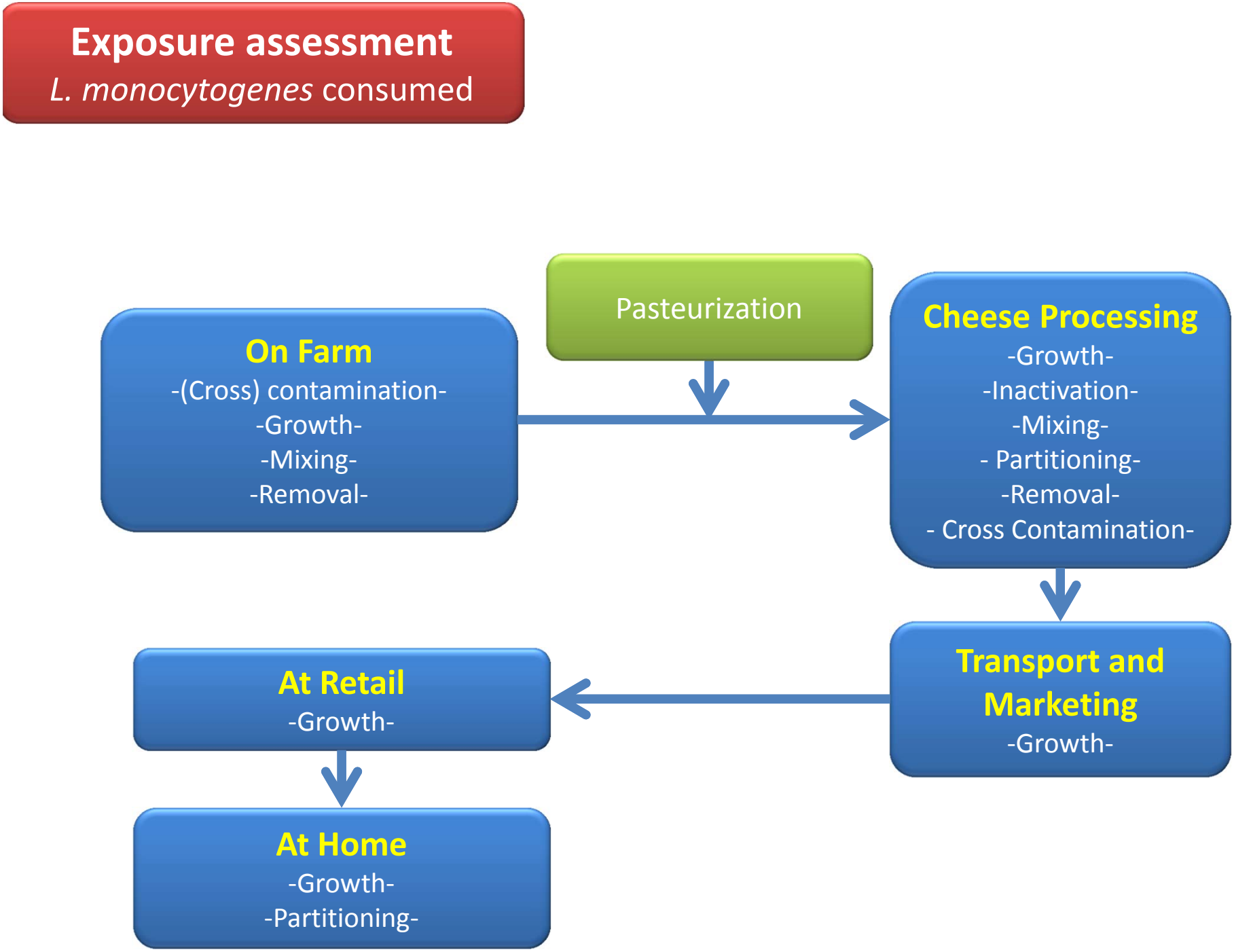
- Dose Response -

- Adapted from the FAO/WHO (2004) risk model
- Exponential dose-response models considering uncertainty

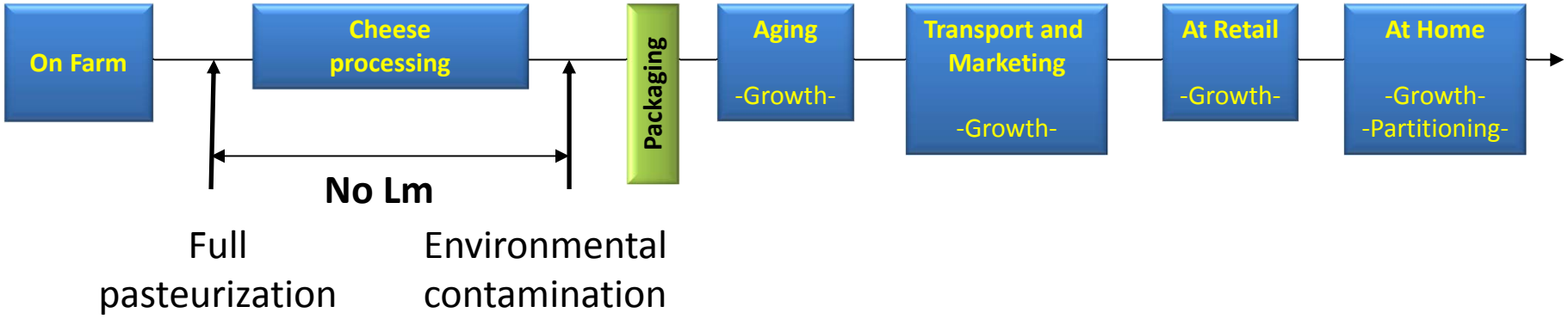


Blue: Susceptible population

Red: Non-susceptible population

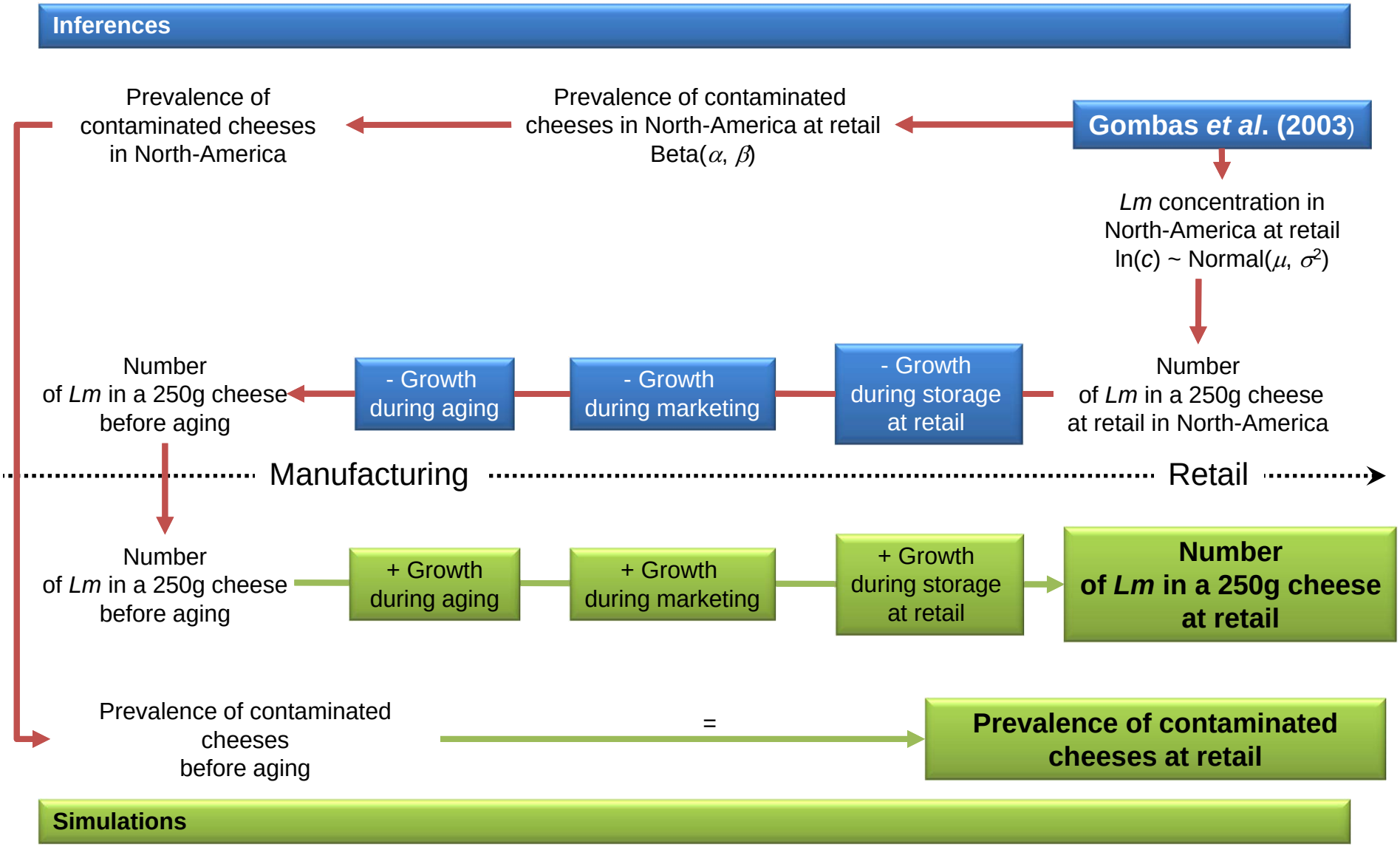

Exposure assessment
L. monocytogenes consumed
On Farm
-(Cross) contamination-
-Growth-
-Mixing-
-Removal-
Pasteurization
Cheese Processing
-Growth-
-Inactivation-
-Mixing-
- Partitioning-
-Removal-
- Cross Contamination-
Transport and Marketing
-Growth-
At Retail
-Growth-
At Home
-Growth-
-Partitioning-

Baseline Model

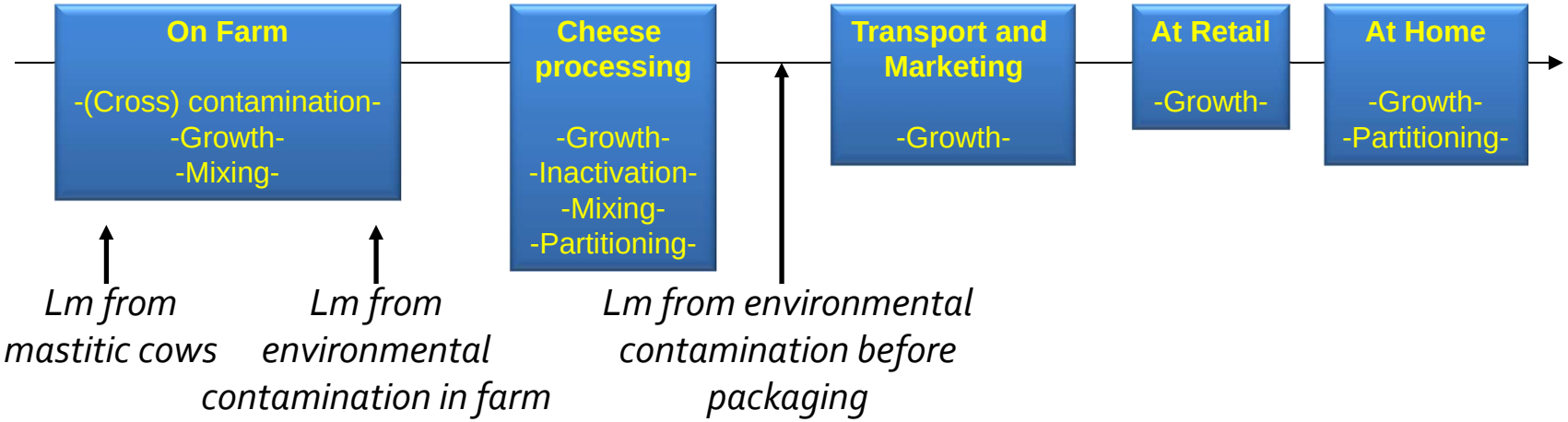


- No bacteria from milk ("full" pasteurization)
- Environmental contamination before aging
  - Prevalence and level inferred from Gombas et al, 2003 (+ backcalculation)
- Bacterial growth from contamination to consumption
  - Lag phase: Relative Lag Time concept
  - Growth during ripening: complex model considering T, pH, a_w and interactions
  - Growth during aging: square root model
  - Growth in solid media (*vs*. liquid) is considered
  - Parameters: meta-analysis of the available literature data
- Partition from serving to serving

Environmental Contamination



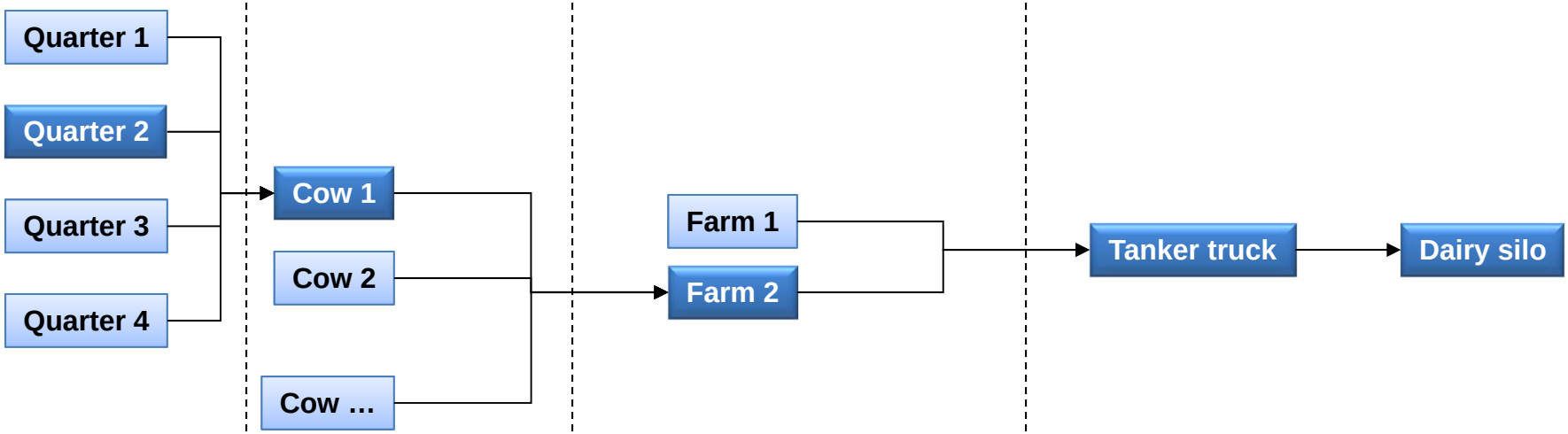
Alternative Scenario: Raw-milk Cheeses



- Includes a farm model with
  - Mastitic cows and/or environmental contamination on farm
  - Mixing of milk from various cows
  - Growth in milk: in farm tank, tanker truck and dairy silo
- Growth in cheese considers the lower pH in “traditional” cheese process and regulatory requirement of at least 60 days storage prior to retail
- Considering additionally
  - Partition during cheese formation
  - Inactivation / Growth in cheeses during ripening

Milk Contamination

Process



Data

- Level of contamination in raw milk from mastitic cow
- Number of infected quarters given mastitis
- Yield reduction given mastitis

- Probability of mastitis in the herd given a positive bulk tank
- Number of mastitic cows on *L. monocytogenes* positive farm

- Number of cows per farm
- Milk production
- Prevalence of positive farm bulk tank
- Level of contamination in positive bulk tank
- Storage time and temperature in farm bulk tank

- Growth characteristics
- Storage time and temperature in tanker truck
- Storage time and temperature in dairy silo

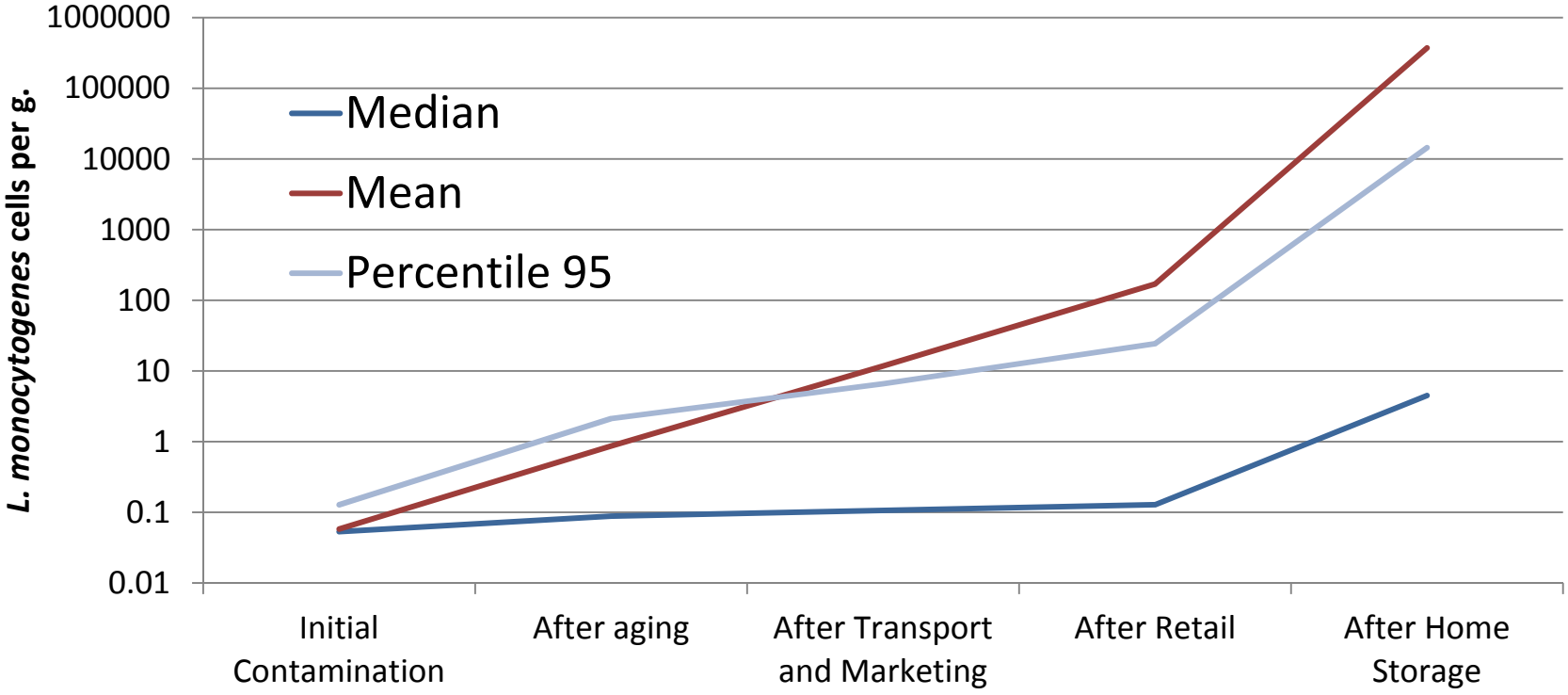
Other Alternative Scenarios

- Raw-milk cheese, no 60-day aging restriction
- Raw-milk cheese, mild treatment that reduces the bacterial load in milk by 3-$\log_{10}$
- Raw-milk cheese, test (and discard if positive) milk at every milking
  - 25 ml of raw milk from the farm tank
- Raw-milk cheese, test (and discard if positive) every lot of cheese
  - Composite sample of 25g from 5 cheeses

RESULTS

Baseline

L. monocytogenes cells per gram at process pathway steps in contaminated cheeses

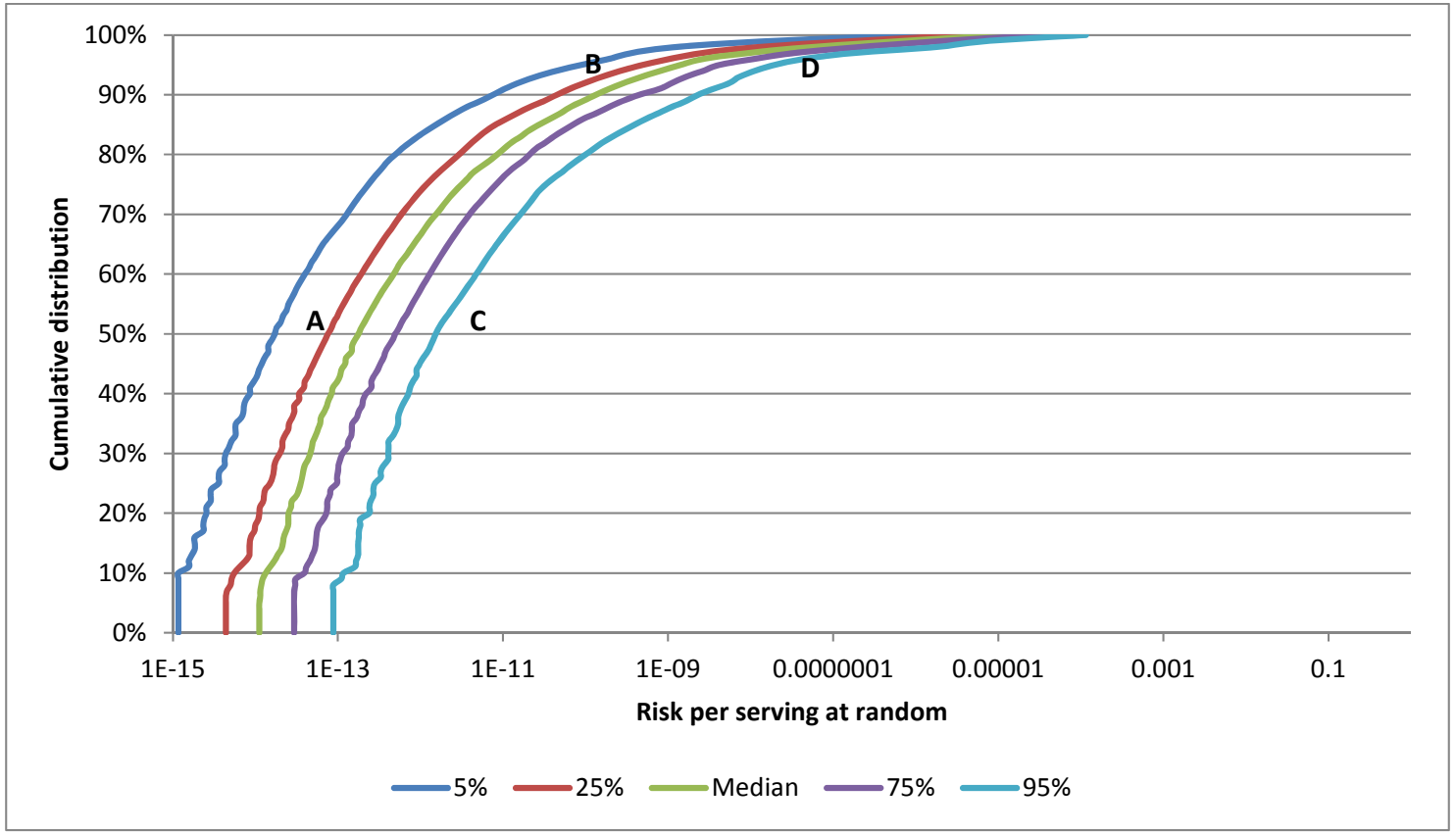


- **Most of the growth occurs after retail**

Mean >> 95th percentile

- **Great (serving to serving at random) variability in this model**

Variability *Vs*. uncertainty



Variability Ratio (B/A) = 8 005 Uncertainty Ratio (C/A) = 9

Overall Uncertainty Ratio (D/A) = 107 933

- **Variability >> (considered) Uncertainty in this model**

Baseline Results
(fully) pasteurized milk, “stabilized” cheese

Estimated number of servings resulting in one case of invasive listeriosis.		
	Canada	**United States**
Elderly	138 million	136 million
Pregnant	56 million	55 million
Immunocompromised	163 million	193 million
General population	7,290 million	8,644 million

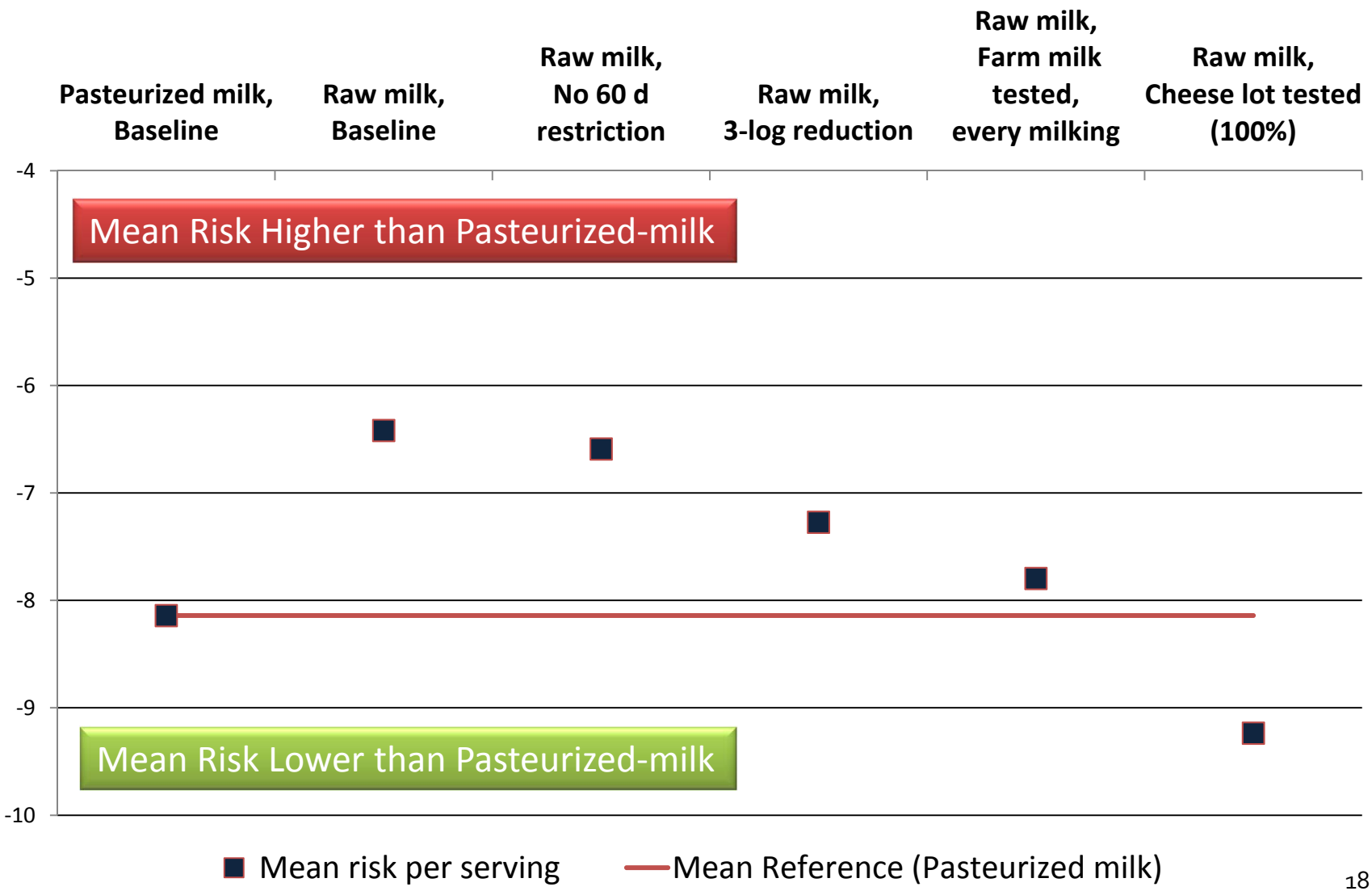
Baseline Results
raw milk, “traditional” cheese

Estimated number of servings resulting in one case of invasive listeriosis. (X-fold increased risk of invasive listeriosis *vs*. pasteurized milk soft-ripened cheese).

	Canada	United States
Elderly	2.6 Million servings (×53)	1.2 Million servings (×112)
Pregnant	1.1 Million servings (×52)	570 000 servings (×96)
Immunocompromised	2.4 Million servings (×69)	1.2 Million servings (×157)
General population	105 Million servings (×69)	55 Million servings (×157)

Alternative Scenarios for Raw Milk cheese

(Elderly population, Canada)



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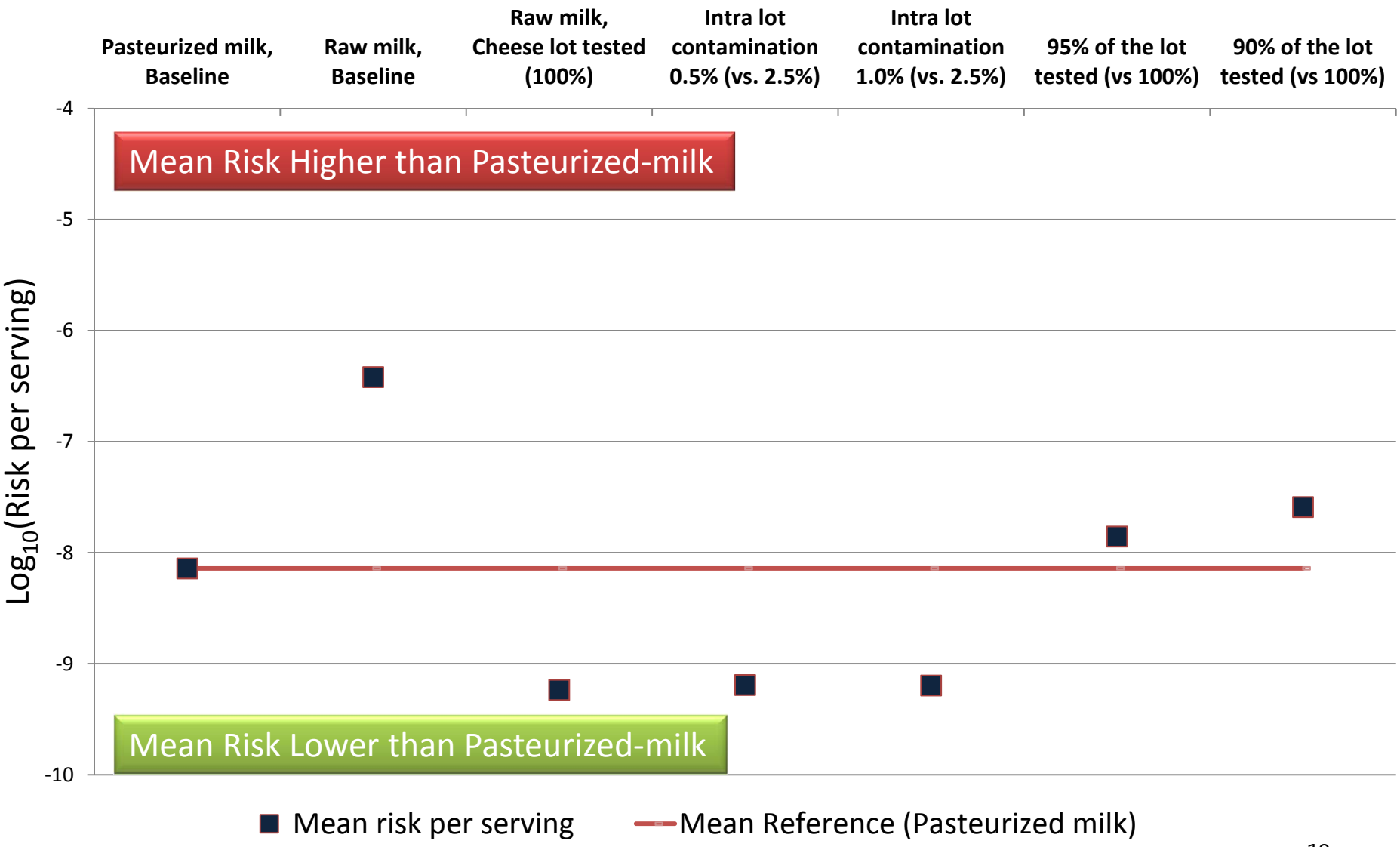


SUMMARY - CONCLUSIONS

“Complex Models to Answer Complex Questions”

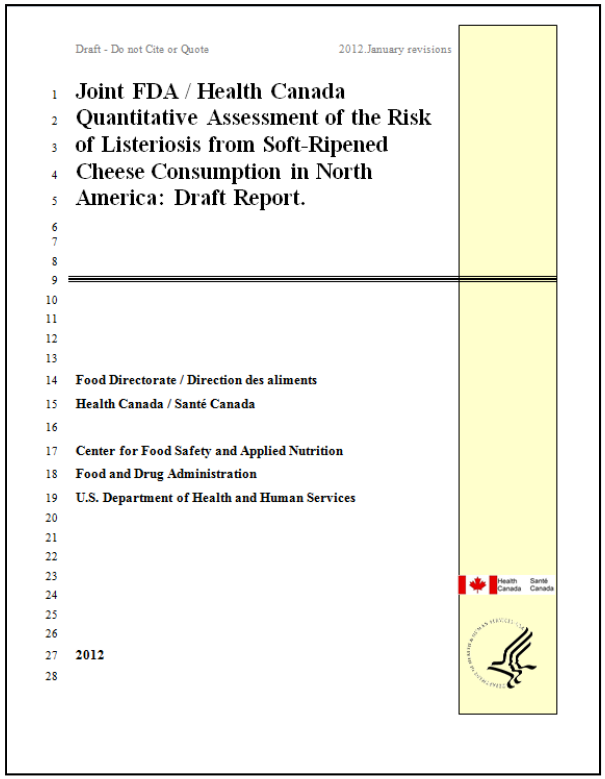
- Extend the FDA/FSIS 2003 Risk Assessment from “store-to-fork” to “farm-to-fork”
- Comparing risk of listeriosis from pasteurized- *vs*. raw-milk cheese needed to consider
  - A full farm to fork model
    - Contamination in farm vs. in-plant contamination
  - A complex growth model considering
    - Lag time
    - Traditional vs. Stabilized manufacturing process
    - Interactions between environmental parameters
    - Growth in solid media
- Limitations – Caveats
  - Conclusions limited to the considered pathogen and the considered cheese
  - Dose-response

Take-home message

- Variability in the Risk linked to the subpopulation
  - Within a country: linked to the dose-response
  - Between countries: different consumption pattern, raw-milk prevalence
- Pasteurized-milk cheese:
  - Time / Temperature in refrigerator is the key factor that increases the risk of listeriosis from contaminated cheeses
  - The best strategy is nevertheless to reduce environmental contamination
- The risk from consumption of raw milk made cheeses is much higher than the risk for pasteurized milk cheeses in the U.S. and Canada
  - × 50 to 160 times higher
- The 60 day aging regulation could increase the risk of listeriosis for raw-milk soft-ripened cheeses
- For raw milk made cheeses, testing every cheese lot is the only alternative that reduces the risk below the level of risk observed in pasteurized milk made cheeses

Current / Next step

- ✓ Peer reviewed
- ✓ Draft report made available
- ✓ Public comments
  - Ended April 29th
  - 96 comments posted



Draft - Do not Cite or Quote 2012.January revisions

Joint FDA / Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in North America: Draft Report.

Food Directorate / Direction des aliments
Health Canada / Santé Canada

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

Health Canada Santé Canada

2012

- ➢ Now Considering the comments

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