

Risk Management - Factoring in different interventions and estimating total benefit

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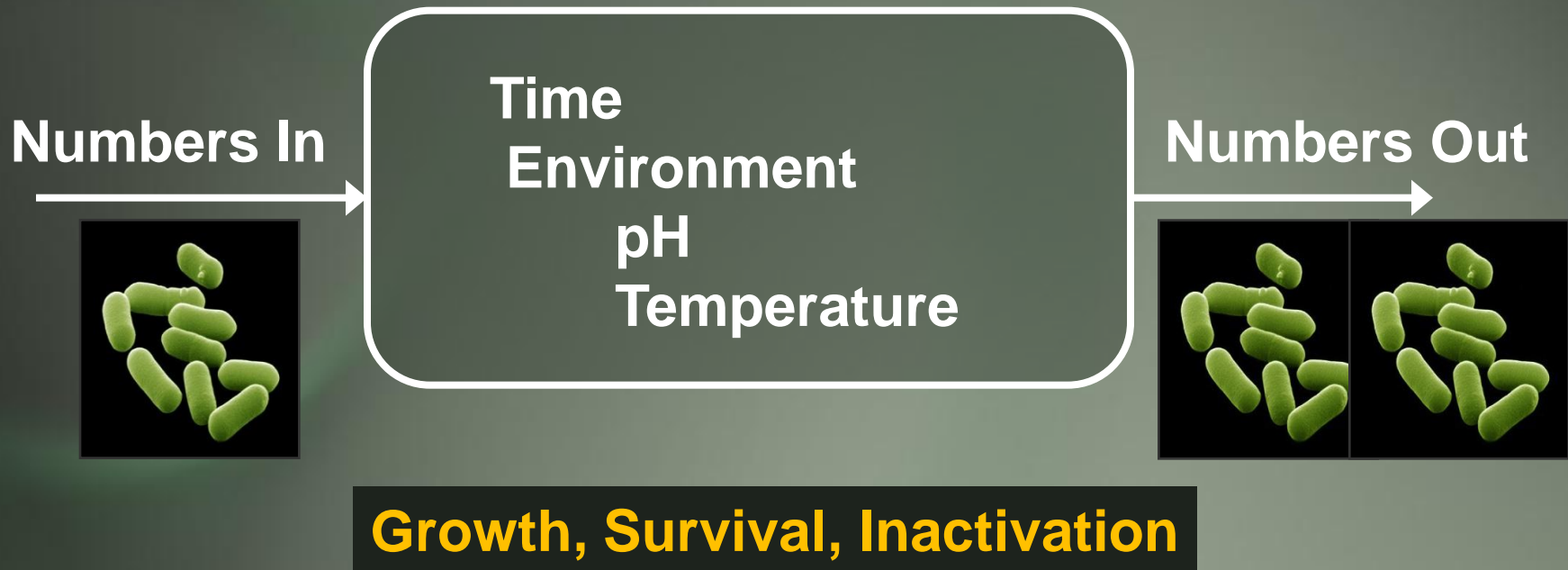
Risk Management—Risk Assessment

- RA a tool to help risk managers make better decisions
- Used when information/knowledge (data) is less than ideal
- Provides an estimate of how accurate/precise knowledge is (data quality)
 - Variation
 - Uncertainty

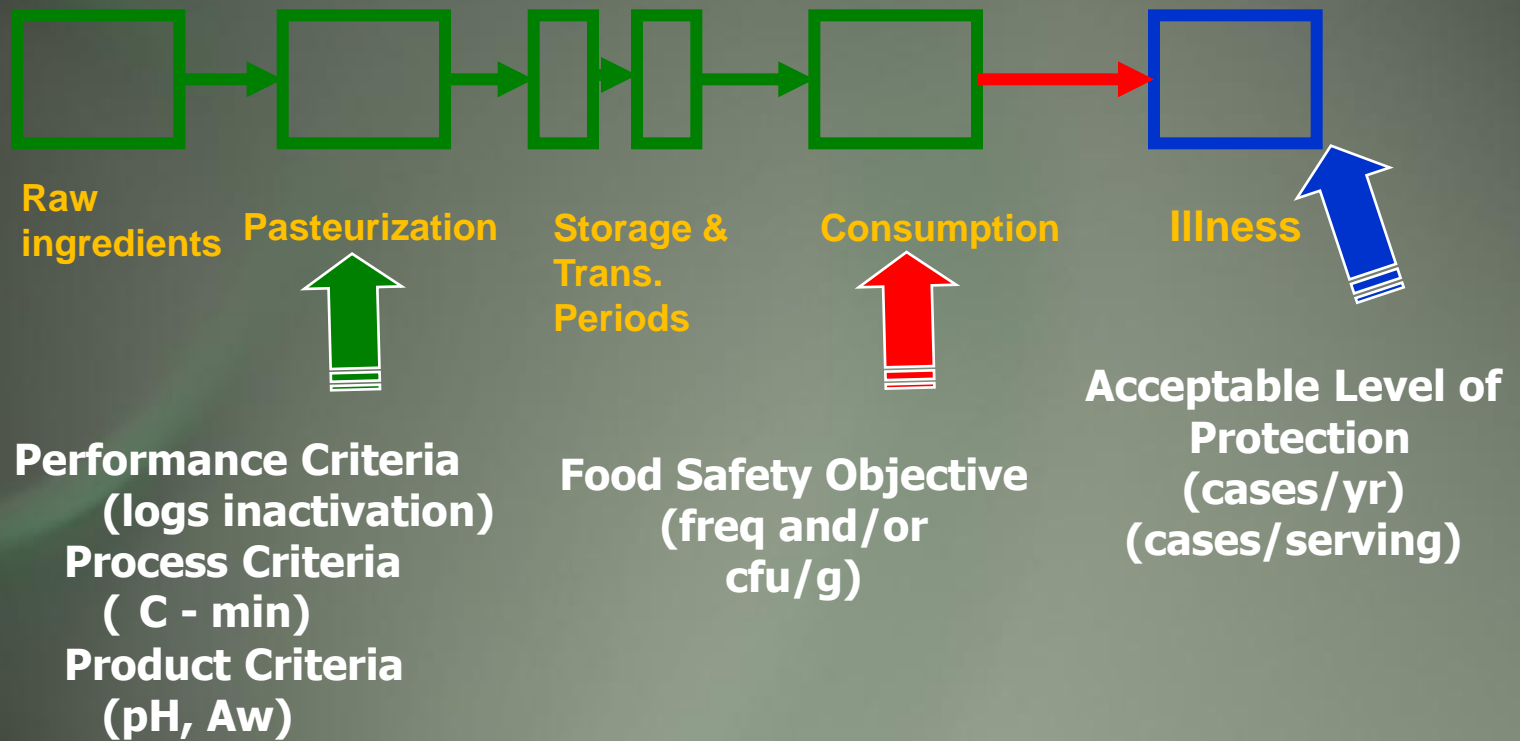
Types of Risk Assessments

- Risk Profile (pre-risk assessment)
- Qualitative risk assessments
- Quantitative risk assessments
- Risk ranking
- Purpose:
 - Identify data gaps
 - Show how factors in a complex process interact
 - Compare different situations/mitigations
 - Estimate the risk/serving or number of cases per year

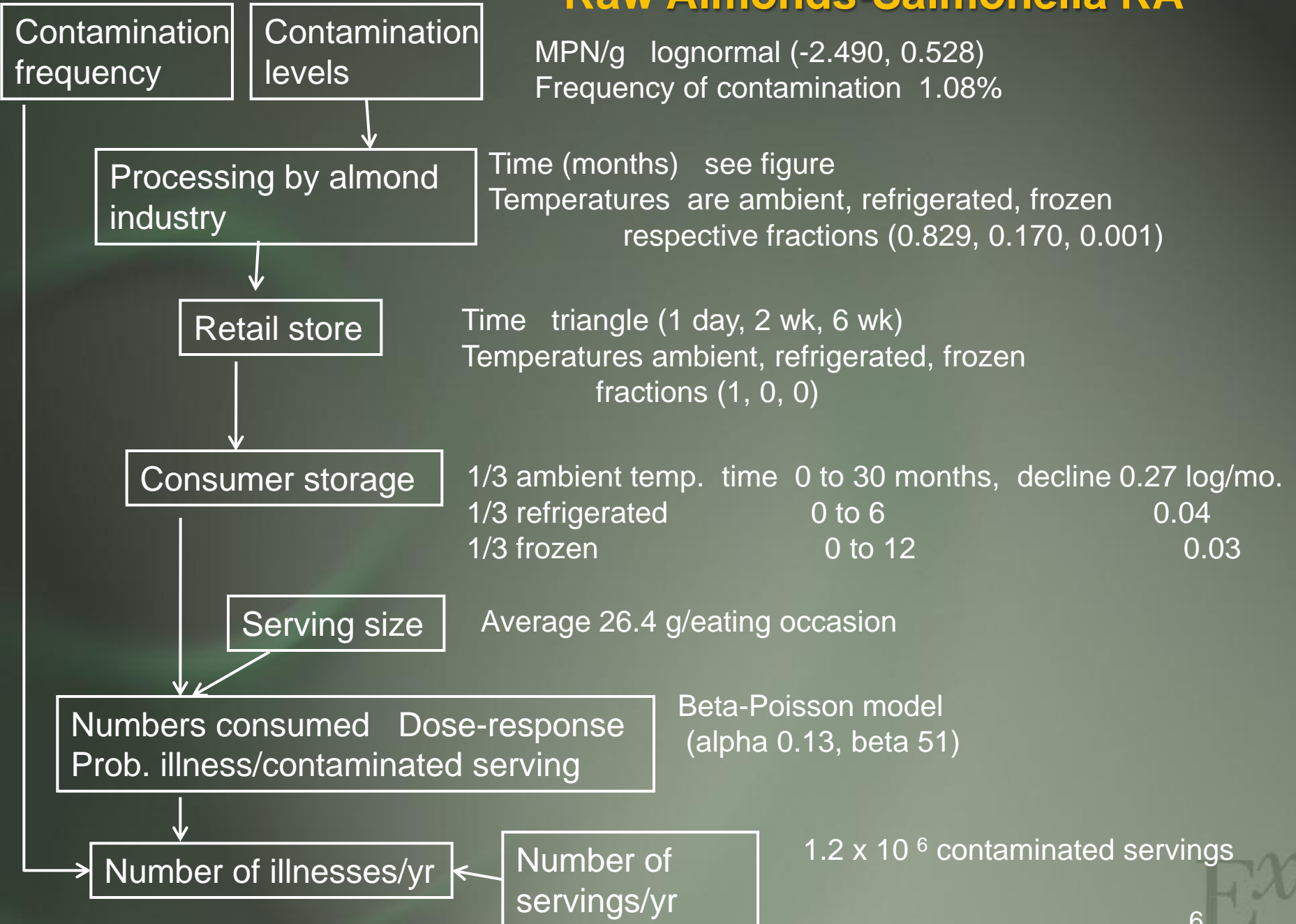
Microbial Unit Operations



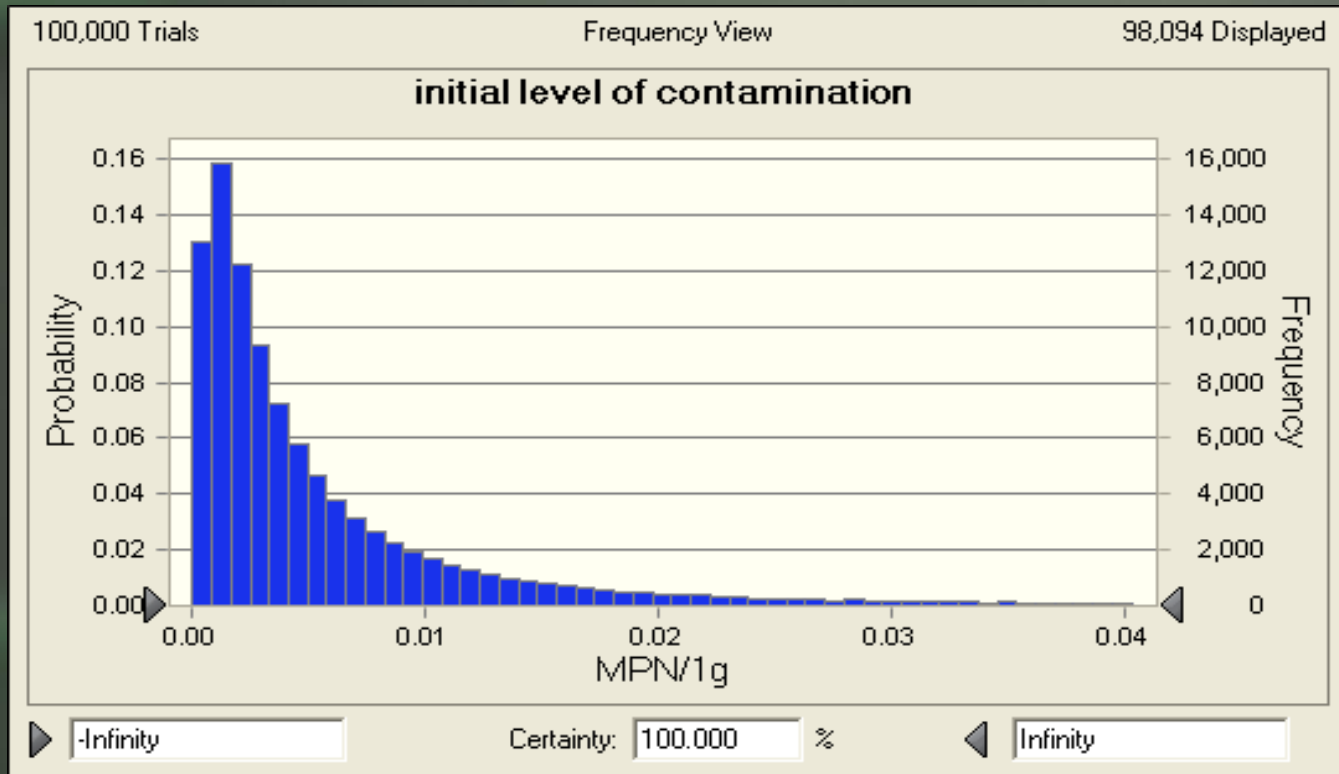
Process Risk Assessment & Risk Management



Raw Almonds-Salmonella RA

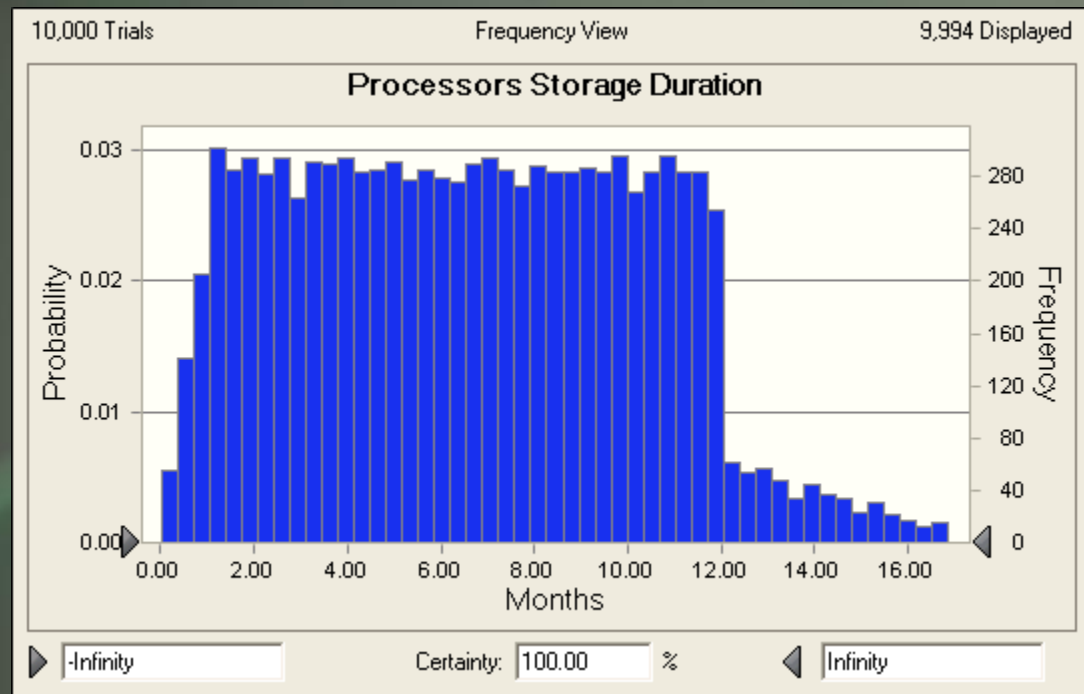


Contamination Distribution

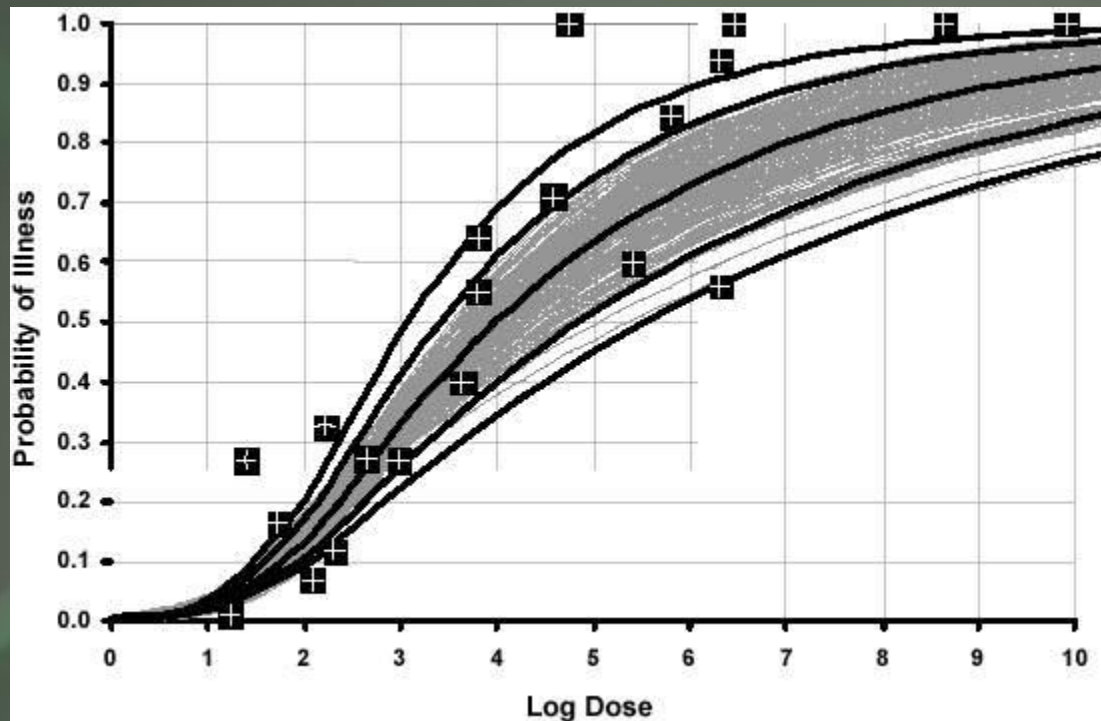


Storage Temperature and Duration

- Handlers (processors) storage time distribution at ambient temperature before retail



Dose-Response Relationship

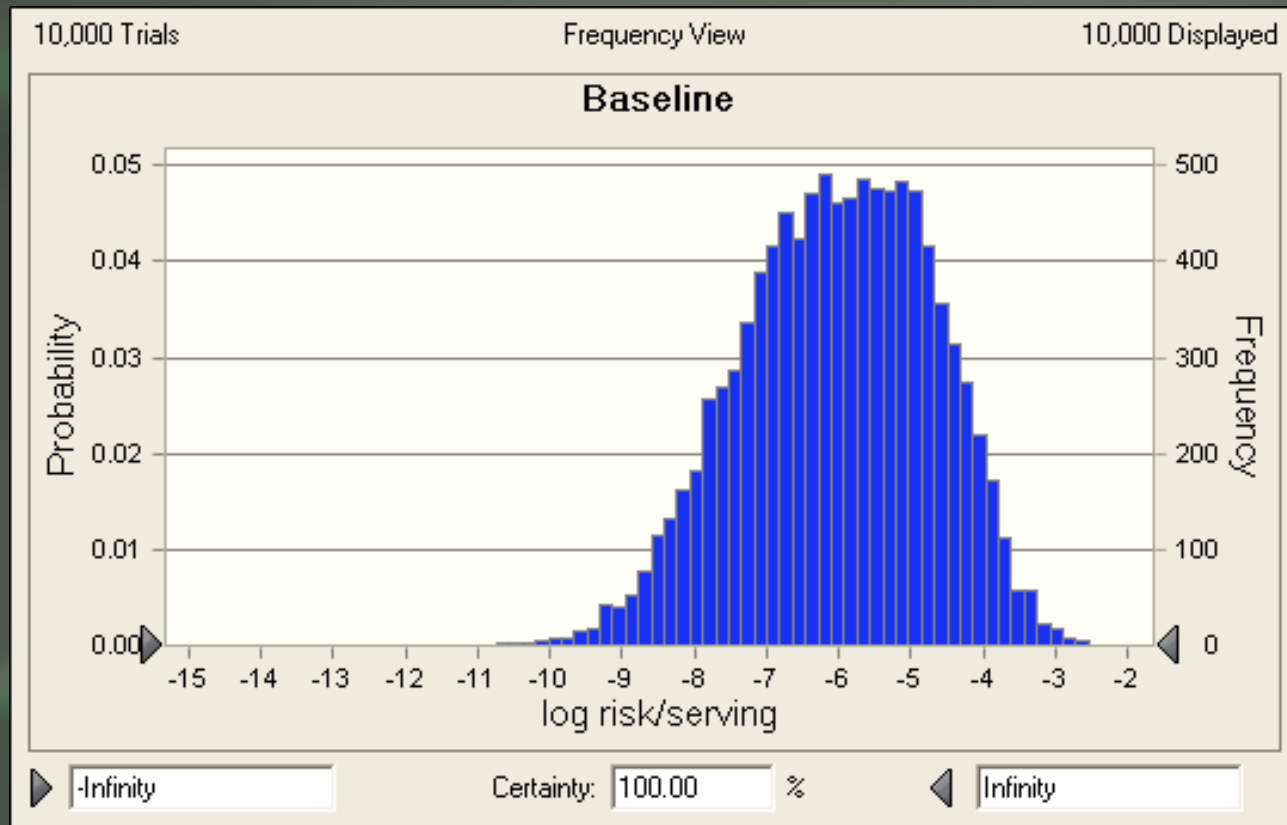


WHO/FAO 2002

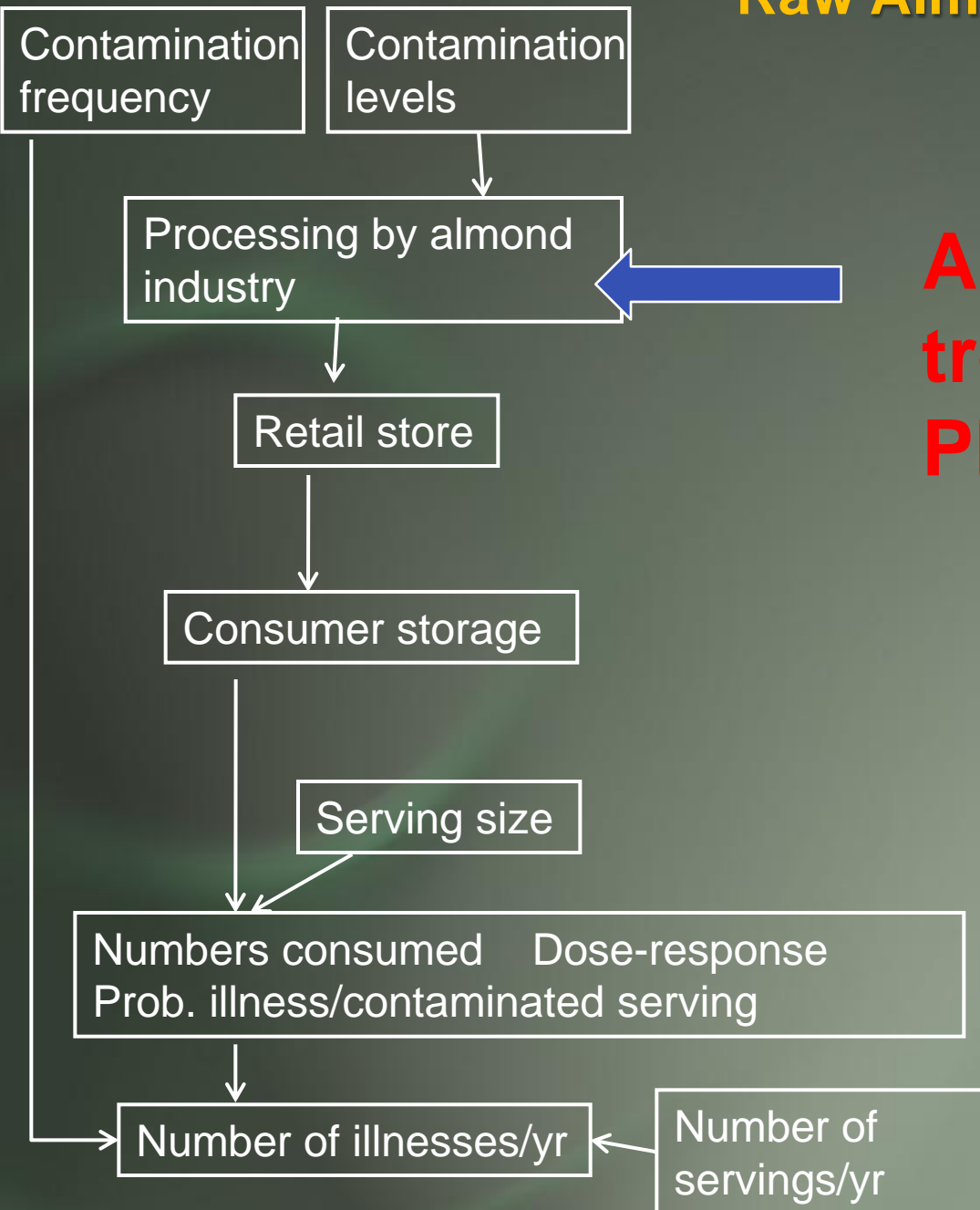
Beta Poisson $P_{ill} = [1 - (1 + n/51)^{-0.13}]$

$P_{100} = 0.13$

Baseline Model Results: Risk Per Serving



Raw Almonds-Salmonella RA

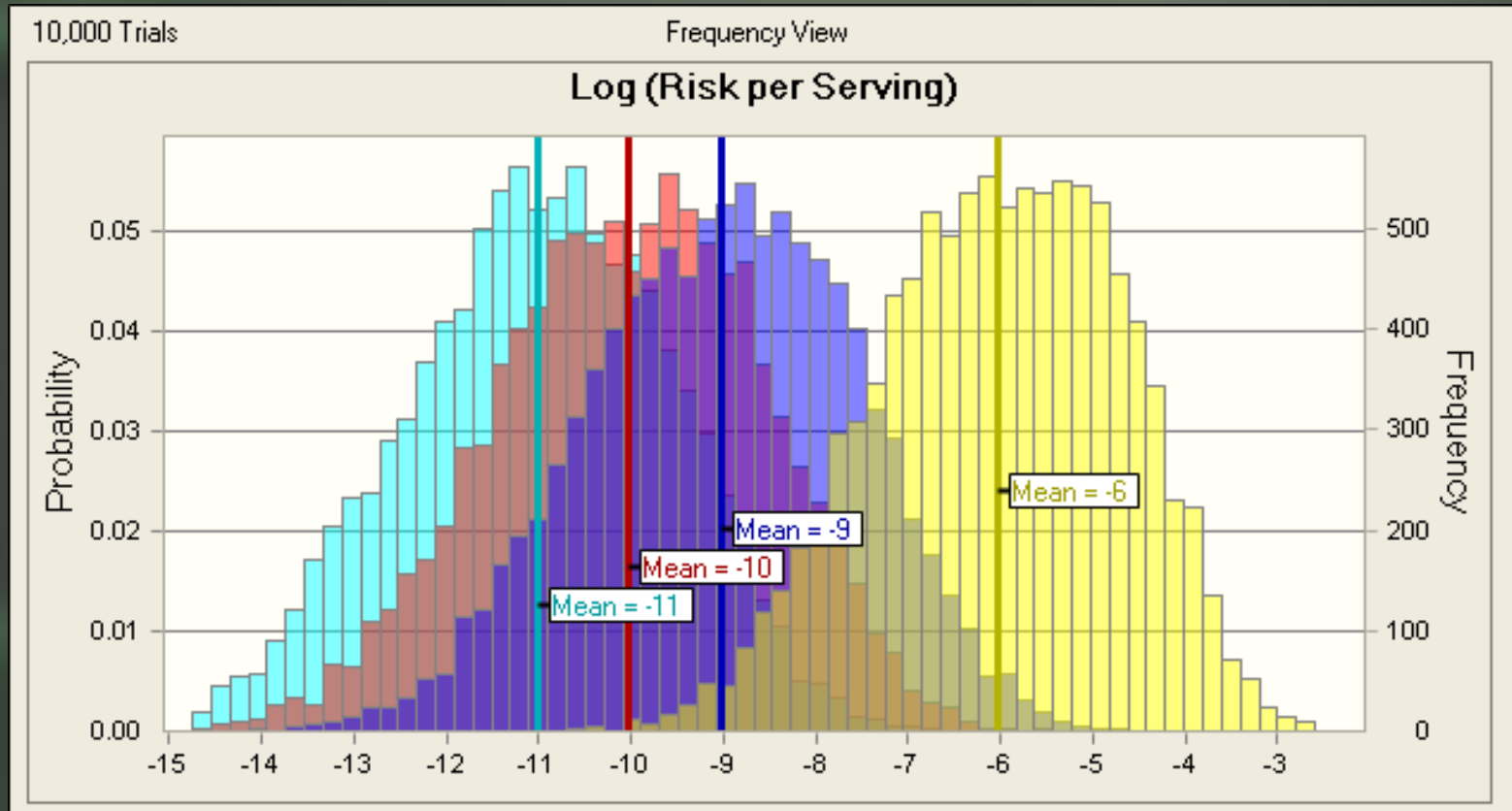


**Add inactivation
treatment
PPO gas**

1.2×10^6 contaminated servings

Potential Risk Reduction by Inactivation Processes

Baseline and 3, 4 & 5 log reductions



Risk of illness per serving (\log_{10})

Risk Model Results

Model & Treatment	Mean # of cases/yr	Probability (%) of		
		>1 case/yr	>10 cases/yr	>100 cases/yr
Baseline model	3	62.68%	36.33%	11.62%
Inactivation treatments				
N(5.0, 0.6)	0.00003	0.01%	0.00%	<0.01%
N(4.0, 0.6)	0.00030	0.17%	0.02%	<0.01%
N(3.0, 0.6)	0.0029	2.92%	0.25%	0.01%
N(5.4, 0.6) (99% > 4.0)	0.00001	<0.01%	<0.01%	<0.01%
N(4.5, 0.2) (99% > 4.0)	0.00009	<0.01%	<0.01%	<0.01%

ABC's goal is to demonstrate to FDA that treated almonds meet the standard to be labeled “pasteurized.”

- Food Drug & Cosmetic Act:
Sec. 403(h)(3) [21 USC 343] – Misbranded as pasteurized unless--
(3)(B)(i) such food has been subjected to a safe process or treatment that—
(I) is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganisms of public health significance that are likely to occur in the food;
- NACMCF (2004)
Any process, treatment, or combination thereof that is applied to food to reduce thermoresistant microorganism(s) of public health significance to a level that is not likely to present a public health risk under normal conditions of distribution and storage.

Appropriate Quantitative Criterion?

- 1998 Juice rule for *E. coli* O157:H7
 - “5 log reduction ...yearly risk of illness to less than 10^{-5} , assuming consumption of 100 ml of juice daily”
 - We calculated this as 3×10^{-8} illness/serving
- *Salmonella* on almonds
 - Average risk of 1×10^{-10} cases/serving with minimum 4-log treatment

In Summary

- **A process risk assessment can help:**
 - Determine of level of risk in an existing
 - Design or modify a process to achieve a specified level of risk
 - Evaluate different treatments/mitigations
 - Create a HACCP plan
 - **Assure public health and brand protection**