



Industry Data Examples Real Data from 3 Large Food

Companies

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Objectives

- Provide an overview of environmental monitoring for pathogens in food plants
- Provide awareness on the significance of positive findings for environmental monitoring programs



Agenda

- > Background
- > Benchmarks
- Review of Results
- > Conclusions



Regulatory Science

"The science needed to assess and evaluate a products safety, efficacy, quality and performance."

Margaret A. Hamburg FDA Commissioner



What is an Environmental Monitoring Program?

The objective of the EMP is to detect & eliminate potential growth niches before pathogens can contaminate product contact surfaces or product

Verification of GMP and sanitation programs



What is an Environmental Monitoring Program?

Find It, Fix It

Seek and Destroy



Zones

✓ Zone 1

✓ Product Contact Surface (PCS) in direct production or high hygiene areas

✓ Zone 2

✓ Non-PCS adjacent to or within close proximity to PCS within production area

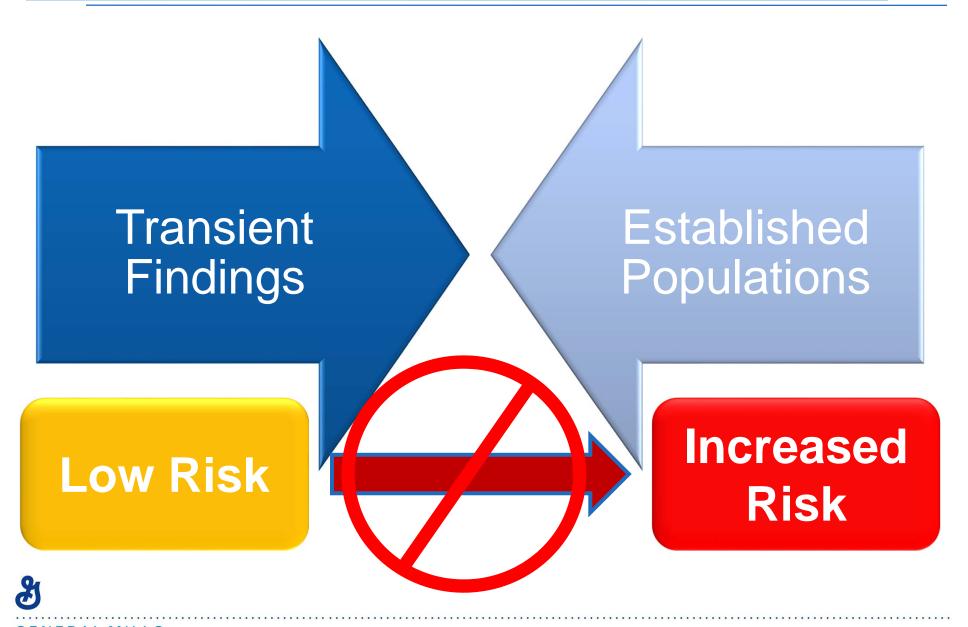
✓ Zone 3

✓ Non-PCS more distant from PCSs and process areas outside of production

✓ Zone 4

✓ Areas outside of the process area (e.g., employee entrance, locker room warehouse, loading dock).

Microorganisms in the Environment



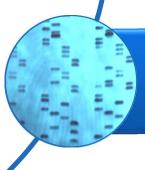
What defines an Established Population?



Repeat findings



Difficult to eliminate



Genetic match



Reaction to Positive Sites





Is a Positive Good or Bad?



Positive Findings can be both Good and Bad

If we find it, we can fix it

Too many findings may indicate a problem

BENCHMARK

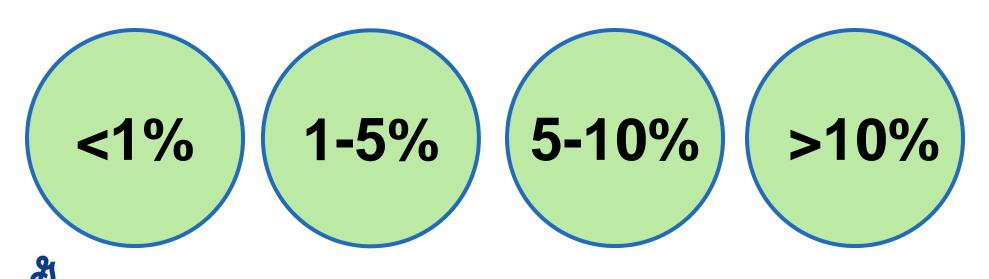
Product: Dry Ready-to-Eat

Organism: Salmonella

Zone: 3

Sampling: Routine

How many positive samples are too many?



BENCHMARK

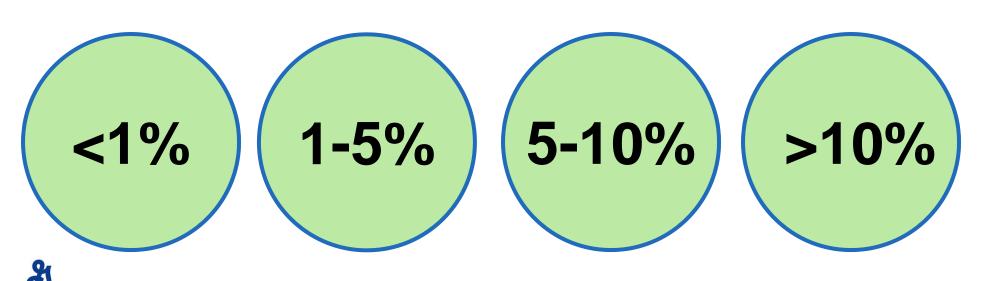
Product: Dry Ready-to-Eat

Organism: Listeria sp.

Zone: 3

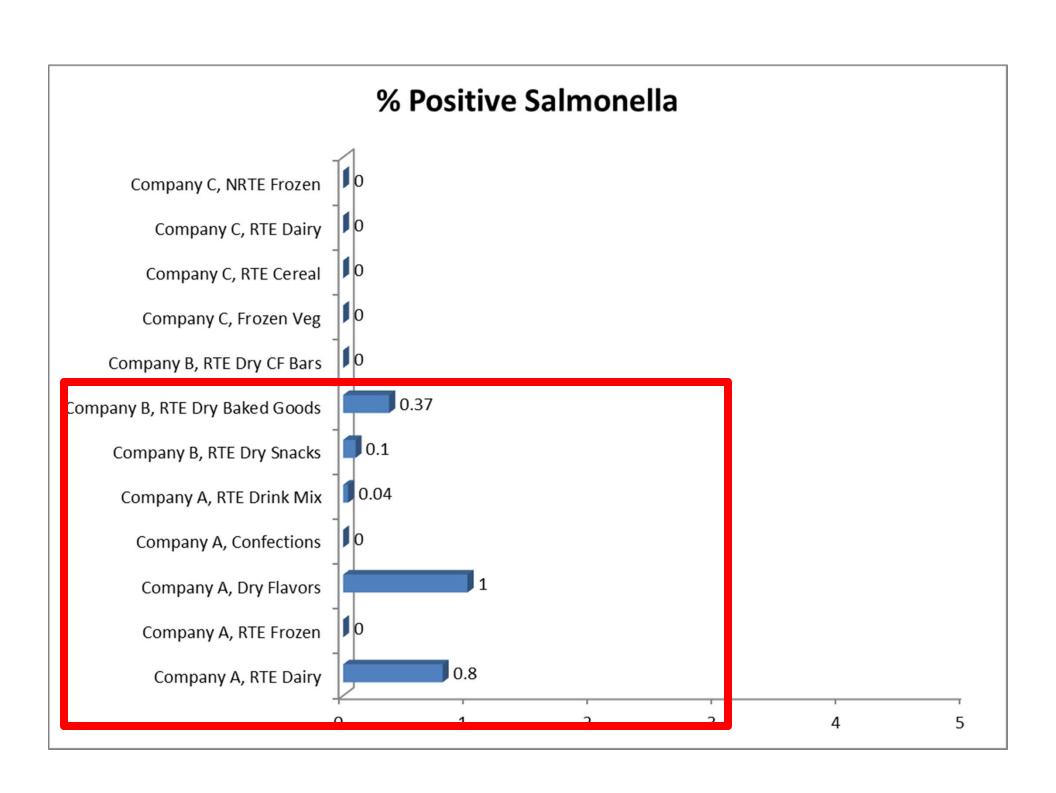
Sampling: Routine

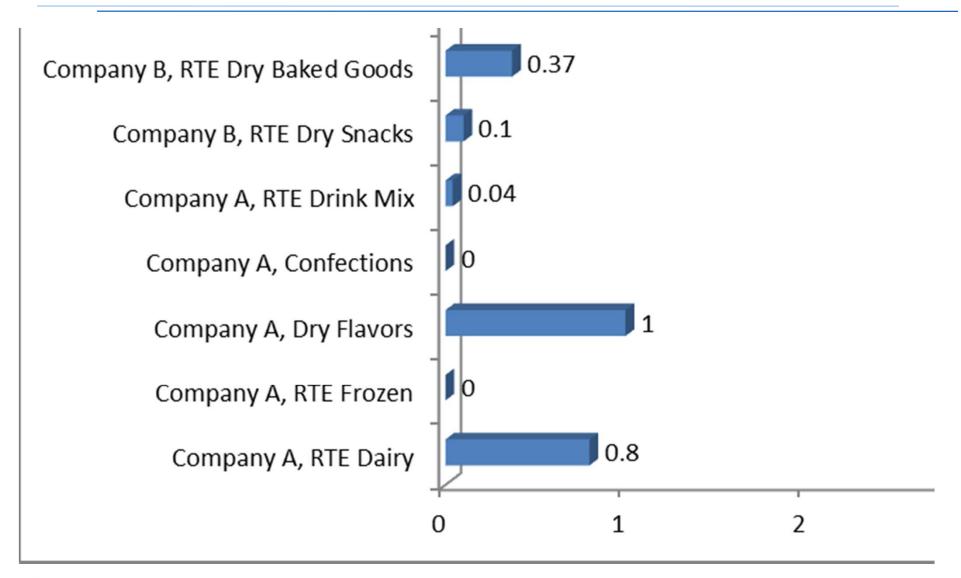
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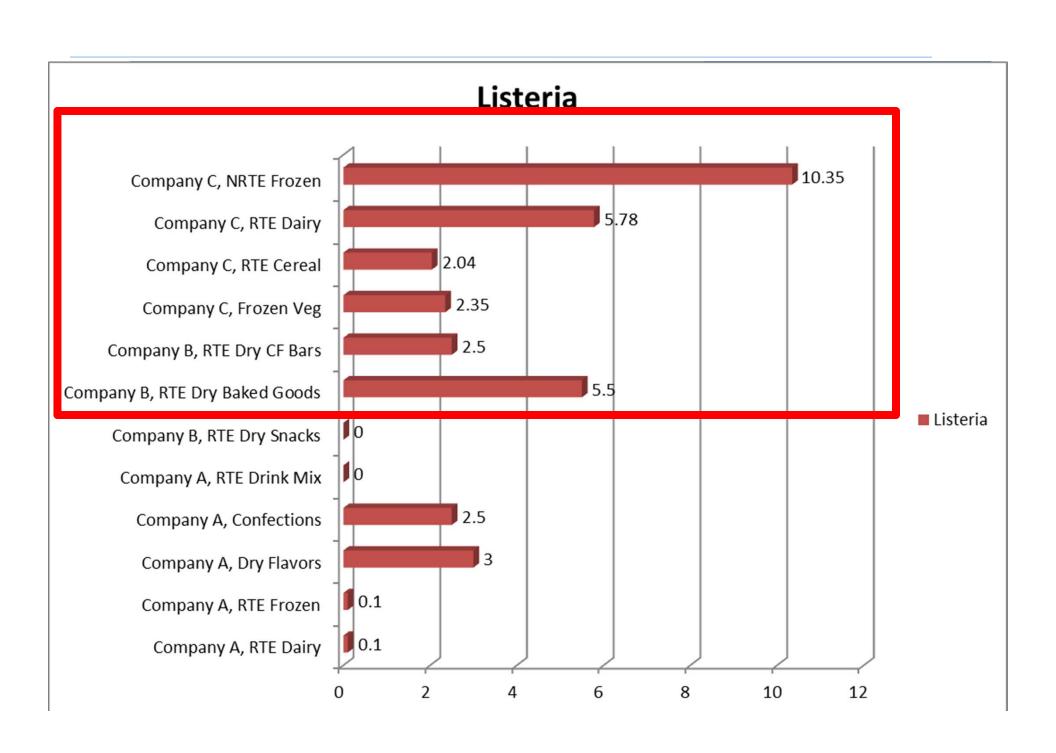
RESULTS

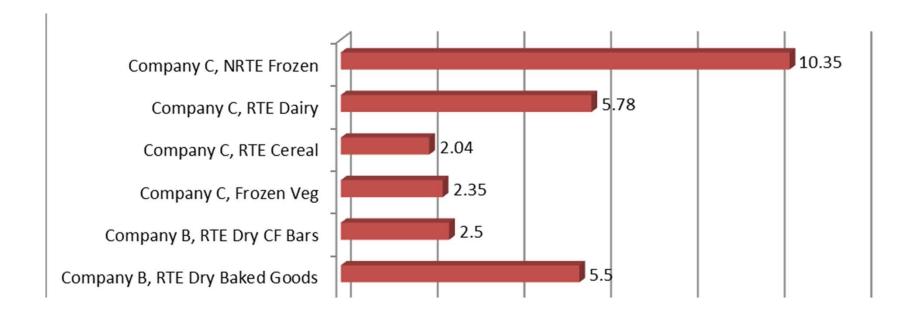






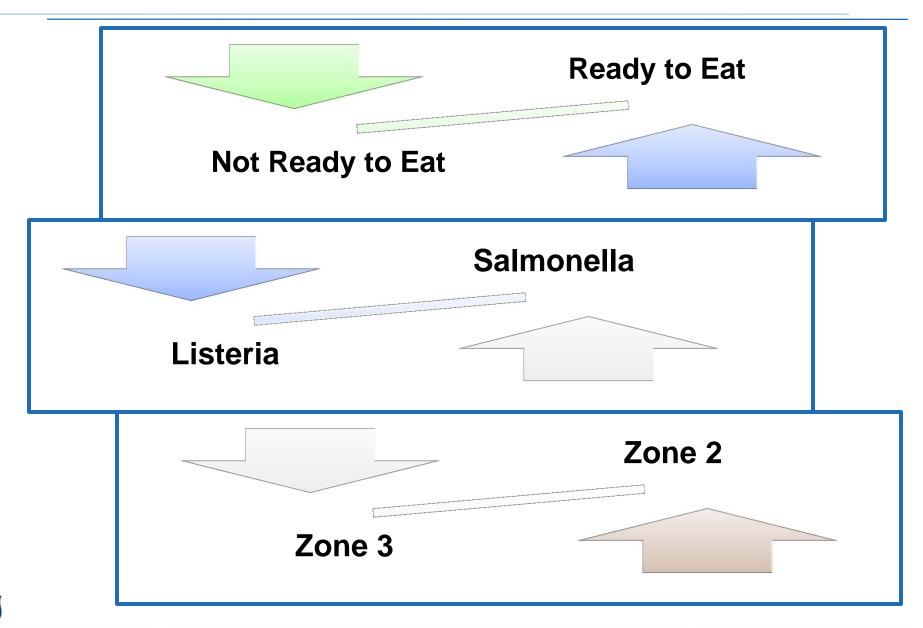








Context





Conclusions

Environmental monitoring is a key verification program

Good programs are designed to find issues

Not all positive samples indicate a significant issue



Thank You

