

PREVENTING THE NEXT CASE STUDY

Tools of the Trade

June 7, 2008

AFDO Workshop

Scott Hood



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GENERAL MILLS

HEADLINES

CNN.com /US

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updated 7:30 p.m. EDT, Thu November 1, 2007

E. coli fears prompt recall of millions of frozen pizzas

find a local business
locallookin

Reporter: KKTU

WASHINGTON - A popular snack food sold nationwide is being recalled because of concerns about contamination.



History

“Those who cannot learn from history are doomed to repeat it.”

George Santayana

“What we learn from history is that we learn nothing from history.”

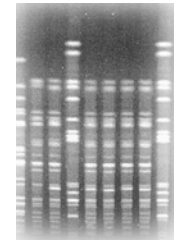
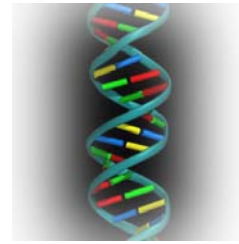
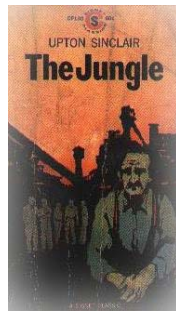
George Bernard Shaw

“History will be kind to me for I intend to write it.”

Winston Churchill



A Brief History of Food Safety



1860s

1906

1953

1960s

1993

Food & Drug Act
Meat Inspection Act

HACCP Developed



CDC Data on Foodborne Illness






76,000,000 → Illnesses

325,000 → Hospitalizations

5,000 → Deaths



2007 Data

	1999 est	2007	2007 est
<i>Salmonella</i>	1,400,000	44,760	1,700,000 
<i>Campylobacter</i>	2,450,000	38,370	1,400,000 
<i>Shigella</i>	450,000	18,750	75,000 
STEC O157	73,000	3,600	72,000 
STEC non O157	36,000	1,700	34,000 
<i>Listeria</i>	2,500	810	1,600 

Participating in History

October 7, 1994



My First Case Study

- **Date:** October 7th, 1994 – Recall Begins
- **Product:** Ice Cream
- **My Role:** Scientist for company making ice cream mix
- **Data:**
 - Estimated 224,000 illness
 - *Salmonella enteritidis*
 - Tankers hauling raw eggs



The First 48 Hours

- The Quality Manager was getting married on October 8th
- Massive sampling of ingredients, products and environment
- Review of records
- Complete understanding of “the process”
- Question everything!

??????????



What did we learn?

- Need deep understanding of the whole supply chain
 - Contamination occurred as the product exited the facility
 - Storage and transportation are essential elements
 - Confirm that practice = policy



Did HACCP Fail?

YES

- Major hazard was not identified in the hazard analysis
- Additional kill step would have prevented issue

NO

- The system could have been managed with good programs



IS HACCP WORKING?

- Traditional Critical Control Points **ALONE** do not protect us from all risks
- Prerequisite Programs are Fundamental
 - Environmental Sampling
 - Good Manufacturing Practices
 - Inspections and Audits
 - Ingredient Programs
 - Training
- Communication is a key



What Have We Learned Since 1994?

- Microorganisms continue to adapt
- Surveillance programs and detection methods keep improving
- HACCP works...when it is part of a comprehensive food safety program



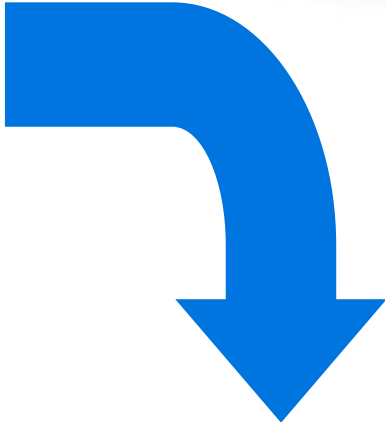
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Risk Assessment

Understanding Plant Practices



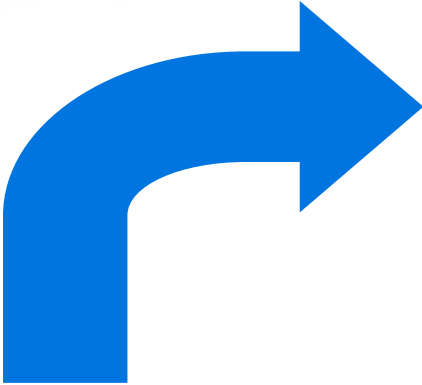
Validation of Assumptions



Setting Priorities



Communication



**Beyond
HACCP**



at General Mills

- Platform Risk Assessment
 - All Plants/All Platform
 - Performed at least 2 times per year

- Does the plant follow the company standard?
- Have there been any positive findings?
- Do audits indicate any conditions of concern
- +
- Intrinsic properties of the product

= Pathogen Risk Score



Pathogen Risk Score

Inherent Risk vs Managed Risk



Canned Food

Product supports growth

Highly regulated

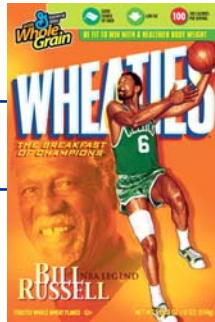
Consumer cooking

Dry Cereal

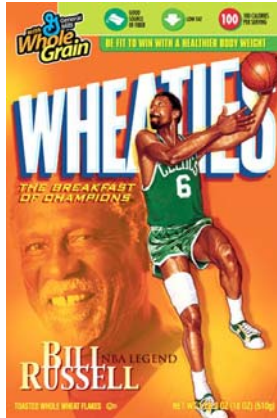
Product does not support growth

Minimally regulated

No consumer cooking



Pathogen Risk Score



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IF

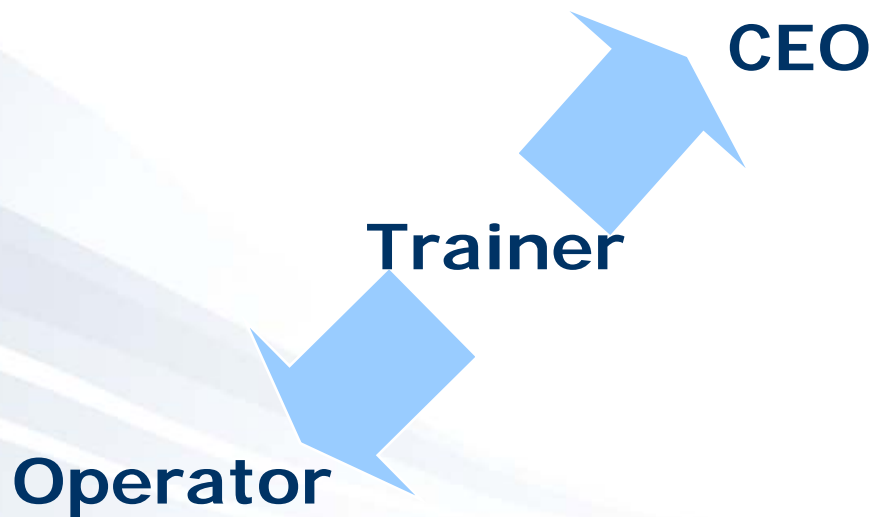


- Environmental Monitoring Plans not in Compliance
- Significant Findings during Environmental Monitoring
- Lack of Control of Incoming Ingredients



Training

- Food Safety is Simple
- Communication can be hard
- Get the right message to the right people



DEEP 6

Design

Eliminate

Exclude

Protect

Salmonella

Listeria

B. cereus

Clostridia

Staph

E. coli



DEEP 6

- **Design:** Product properties designed to prevent growth of pathogens
- **Eliminate:** Kill Step
- **Exclude:** Environmental and Ingredient Programs
- **Protect:** Prevent growth during storage and transportation



Ice Cream Case Study

- What Failed (**Design, Eliminate, Exclude, Protect**)?
 - Mix should have been pasteurized again
 - **Eliminate:** Needed another kill step
 - **Eliminate:** Appropriate cleaning for Tankers
 - Tankers should not have been hauling eggs
 - **Exclude:** Keeping pathogens out of tankers



Bug Hunt

“If we keep them out of the plant, we will keep them out of the product.”

Tom Smith

General Mills, circa 1995

“It’s a hunt for wild game!”

Don Zink

FDA, 2007



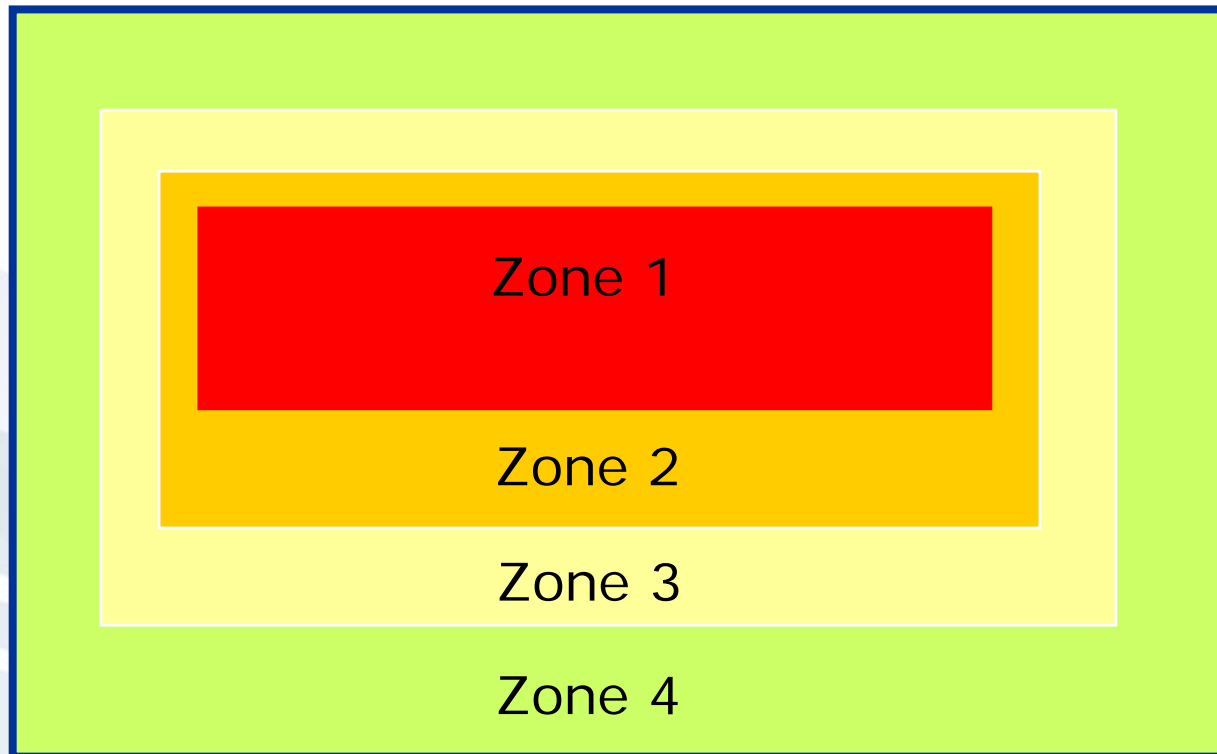
Environmental Monitoring

- A key prerequisite program for HACCP
- Do not create disincentives if the plant finds pathogens
- When there are findings, focus on strategies to eliminate the pathogens
- History Shows
 - *Salmonella* in dry, ready-to-eat foods
 - *Listeria monocytogenes* in refrigerated foods



Best Practices

- Microorganisms in Foods 7
 - 2002, ICMSF



Guidance Documents

- Industry Working Together
- Learning from each other
- Common Practices
- Communication

Leverage Associations

- GMA
- University of Georgia
- IFT
- IAFP



Predicting the Future

- History will be repeated
- HACCP will not work if the food safety programs are not strong
- Microorganisms will continue to adapt
- Methods will continue to improve

We can
Write History

We can't
Stop Nature



THANK YOU



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