

Lessons Learned & Insights

Sarah Geisert
APEC FSCF PTIN Developing Food Safety
Plans for the Supply Chain Module

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Asia-Pacific
Economic Cooperation

Goals for Today

- Review recent US food safety incidents
- Identify some common themes & challenges
- Explore Change Management application
- Generate new ideas



Recent US Recalls due to Salmonella

**Peanut
Butter 2007**

Salmonella contamination at manufacturing plant due to plant infrastructure issues. Large consumer products company.

**Peanut
Containing
Products
2009**

Salmonella in peanuts/peanut butter due to infrastructure issue, intermingling raw and processed & economically motivated actions to ship contaminated product. Small ingredient supplier.

**Hydrolyzed
Vegetable
Protein 2010**

Salmonella detected in HVP by customer. Investigation identified equipment sanitation deficiencies and environmental findings. Small ingredient supplier.



Peanut Butter 2007 – Lessons Learned

First salmonella outbreak in the U.S. involving peanut butter. Identified through epidemiological investigation linking illnesses in multiple states. 6 months from first illness to recall. Facility infrastructure/leaky roof identified as deficiencies. Reported 625 people affected in 46 states with on deaths. Reported financial impact \$50-60 MM. Consumer products impacted were limited.

- ❖ **Emergence of Salmonella as a pathogen of concern in low moisture foods. Epidemiology methods gaining in prominence**
- ❖ **Failure to execute prerequisite program fundamentals can have significant public health and financial impact**
- ❖ **“Events” do not have a size discrimination**
- ❖ **Industry collaboration and regulatory acknowledgement advance publication of Grocery Manufacturers Association “Salmonella Control in Low Moisture Foods” .**



Peanut Containing Products 2009 – Lessons Learned

Small supplier impacted over 2,800 products and 250 brands. Identified through epidemiological investigation linking illnesses in multiple states. Numerous facility issues including lack of validated process, insufficient separation of raw and processed and management knowingly shipping product with positive test results. Reported 700 illnesses & 9 deaths. Company bankrupt with total industry costs exceeding \$100 MM. Owner facing criminal prosecution.

- ❖ **Advancing global knowledge and intervention to prevent future issues remains a challenge,**
- ❖ **Failure to execute prerequisite program fundamentals can have significant public health and financial impact**
- ❖ **“Events” do not have a size discrimination. A single ingredient supplier producing at one processing facility generated a very complex distribution chain.**



Hydrolyzed Vegetable Protein 2010 – Lessons Learned

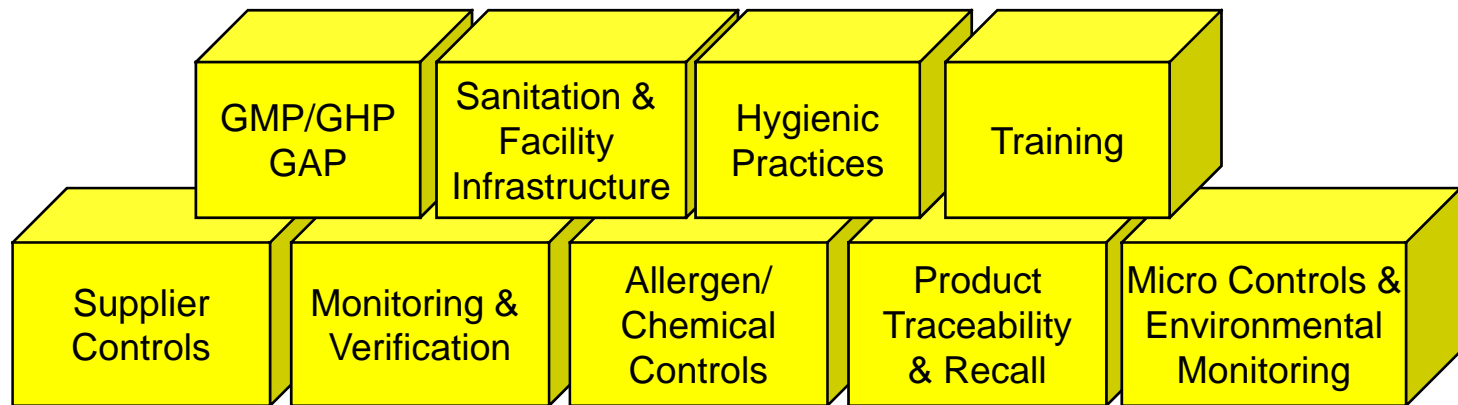
The issue was identified and reported by a consumer product manufacturer and reported to the regulatory agency. This commonly used ingredient exposed many manufacturers to a “single producer” problem because of a failure in their prerequisite programs including sanitation of equipment. Over 180 products recalled. Recalled product went back to September 2009. No illnesses or deaths reported.

- ❖ **While no illnesses were reported, hundreds of products were recalled in early 2010 because of a Salmonella contamination**
- ❖ **Prerequisite program failures in sanitation and environmental monitoring were identified as some of the program deficiencies**
- ❖ **Inability to limit recall to a date or small period to time either because of insufficient data and/or documentation deficiencies**
- ❖ **Risk-based decision by regulatory agency determined products with a validated “kill step” or a filed thermal process would not be impacted**



Basis for HACCP System - Prerequisites Programs

HACCP



Prerequisite Programs

+

Operational Practices

+

Critical Control Points

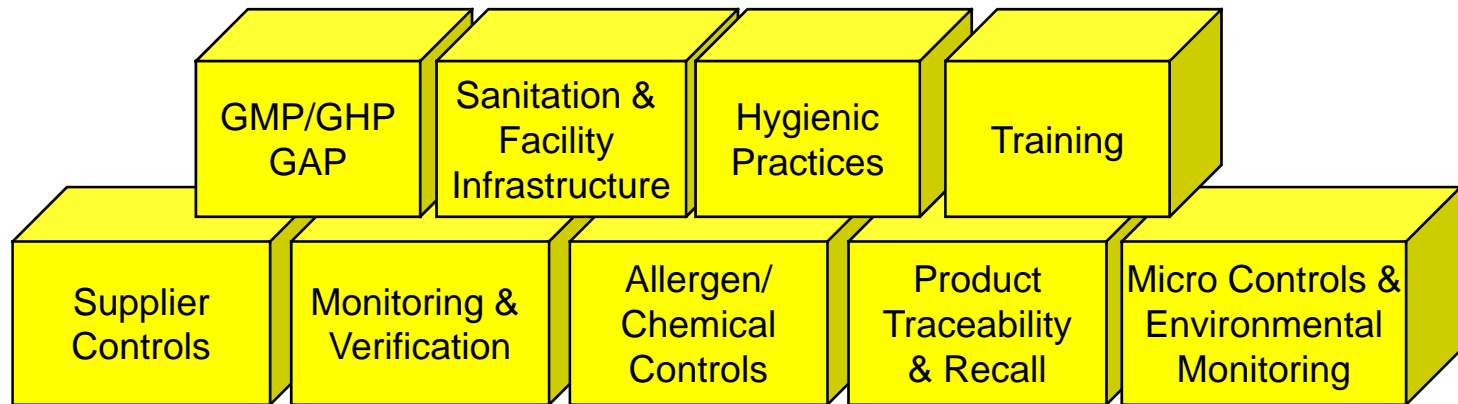
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Risk Management



Basis for HACCP System - Prerequisites Programs

HACCP



Prerequisite Programs + Operational Practices + Critical Control Points = Risk Management

Management Commitment and Food Safety Culture



Microbiological Change Management Challenges

1. Current state vs. future goal - maturity of companies food safety knowledge greatly varies complicating education
2. Complexity – numerous microbes with more emerging; requires multiple programs to manage
3. Risk tolerance differences
4. Gaps in education and knowledge transfer not information
5. There are many more....



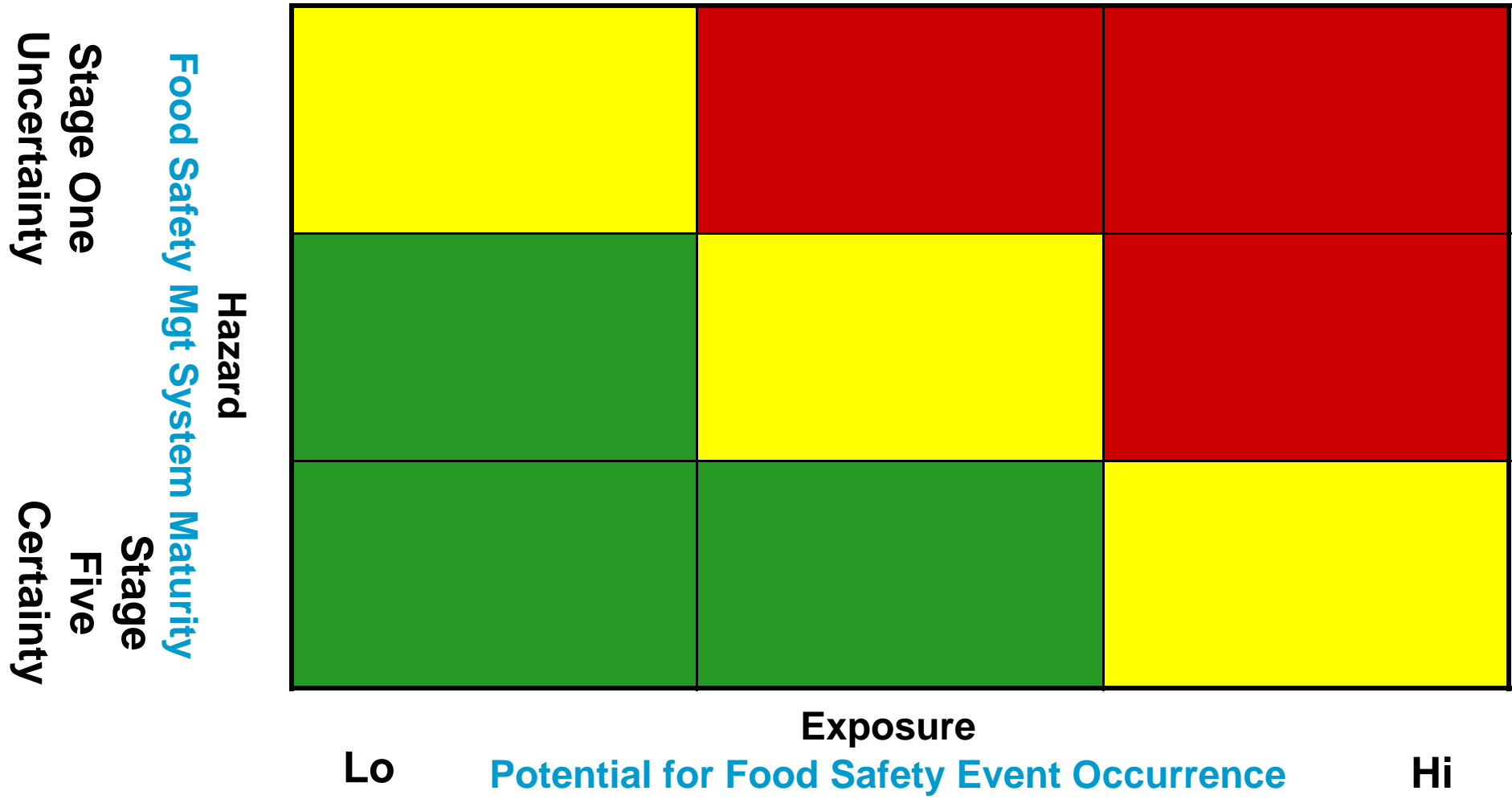
#1 Current State, Future Goal

- Focused assessments can help define path forward
- To efficiently and effectively improve future state, need to know where you are
- Impacts resource allocation
- Supports delivery of sustainable education
- Visual can assist in communication

GOAL: CREATE ROADMAP



Use of Existing Models and Visuals



Create New Axis's

Food Safety Management Maturity Example

- Management maturity category
 - Management understanding and attitude
 - Food safety organizational status
 - Problem handling
 - Metrics
 - Improvement actions
 - Summation of overall organization position
- Stages of development
 - I though V or
 - Uncertainty to Certainty



Food Safety Management Maturity Grid

Measurement Categories	Stage I: Uncertainty	Stage II: Awakening	Stage III: Enlightenment	Stage IV: Wisdom	Stage V: Certainty
Management Understanding and Attitude	No comprehension of food safety/quality as a management tool. Tend to blame food safety/quality department for "food safety/quality problems."	Recognizing that food safety/quality management may be of value but not willing to provide money or time to make it all happen.	While going through food safety/quality improvement program learn more about food safety/quality management; becoming supportive and helpful.	Participating. Understand absolutes of food safety/quality management. Recognize their personal role in continuing emphasis.	Consider food safety/quality management as essential part of company system.
Food Safety/Quality Organization Status	Food safety/quality is hidden in manufacturing or engineering departments. Inspection probably not part of organization. Emphasis on appraisal and sorting.	A stronger food safety/quality leader is appointed but main emphasis is still on appraisal and moving the product. Still part of manufacturing or other.	Food safety/quality department reports to top management, all appraisal is incorporated and manager has role in management of company.	Food safety/quality manager is an officer of company; effective status reporting and preventive action. Involved with consumer affairs and special assignments.	Food safety/quality manager on board of directors. Prevention is main concern. Food safety/quality is a thought leader.
Problem Handling	Problems are fought as they occur; no resolution; inadequate definition; lots of yelling and accusations.	Teams are set up to attack major problems. Long-range solutions are not solicited.	Corrective action communication established. Problems are faced openly and resolved in an orderly way.	Problems are identified early in their development. All functions are open to suggestion and improvement.	Except in the most unusual cases, problems are prevented.
Food safety/quality cost metrics	Reported : unknown Actual: 20%	Reported : 3% Actual: 18%	Reported : 8% Actual: 12%	Reported : 6.5% Actual: 8%	Reported : 2.5% Actual: 2.5%
Food Safety/Quality Improvement Actions	No organized activities. No understanding of such activities.	Trying obvious "motivational" short-range efforts.	Implementation of the multi-step program with thorough understanding and establishment goal for each step.	Continuing the multi-step program and starting to make progress..	Food safety/quality improvement is a normal and continued activity.
Summation of company food safety/quality posture	"We don't know why we have problems with food safety/quality."	"Is it absolutely necessary to always have problems with food safety/quality?"	"Through management commitment and food safety/quality improvement we are identifying and resolving our problems."	"Defect prevention is a routine part of our operation."	"We know why we do not have problems with food safety/quality."



Microbiological Management Maturity Grid

Measurement Categories	Stage I: Uncertainty	Stage II: Awakening	Stage III: Enlightenment	Stage IV: Wisdom	Stage V: Certainty
Management Understanding and Attitude	No comprehension of microbiology as a critical hazard to manage.	Recognizing that microbiological management may be of value but not willing to provide money or time to make it all happen.	While going through development of microbiological control programs learning more about food safety/quality management; becoming supportive and helpful.	Participating. Understand importance of microbiological management programs. Recognize their personal role in continuing emphasis.	Consider microbiological food safety management as essential part of company system.
Process Validation	Unaware of concept.				Documented programs. Verification built into routine activities. Broad understanding of control actions and decision expectations.
Environmental Monitoring Program	Unaware of concept, no program in place.				Robust program with clarity around actions. Prevention is the main concern.
Microbiological based metrics	Established : unknown Transient: unknown				Established : unknown Transient: unknown
Employee Education	No organized activities. No understanding of such activities.				Microbiology management & improvement is a normal and continued activity.
Analytical Method	Do not do any testing. Are unfamiliar with basic techniques.				We use GLP or work with qualified external labs. We understand the range and application of methods available and use them accordingly.



#2 Enormous Complexity

Raw Materials

- Vendor controls and oversight
- Contaminated Ingredients
- No further processing

Environmental Monitoring

- Inconsistency and lack of understanding
- Established pathogens transferred to RTE Foods
- Post process contamination

In-Process Growth

- Identification of microbe of concern
- Lack of process control
- Product abuse

Lack of or Poor Quality Data

- Validation protocols lacking
- Documentation of Validations
- No or minimal finished product testing
- Good laboratory practices



Complexity Within One Program Element

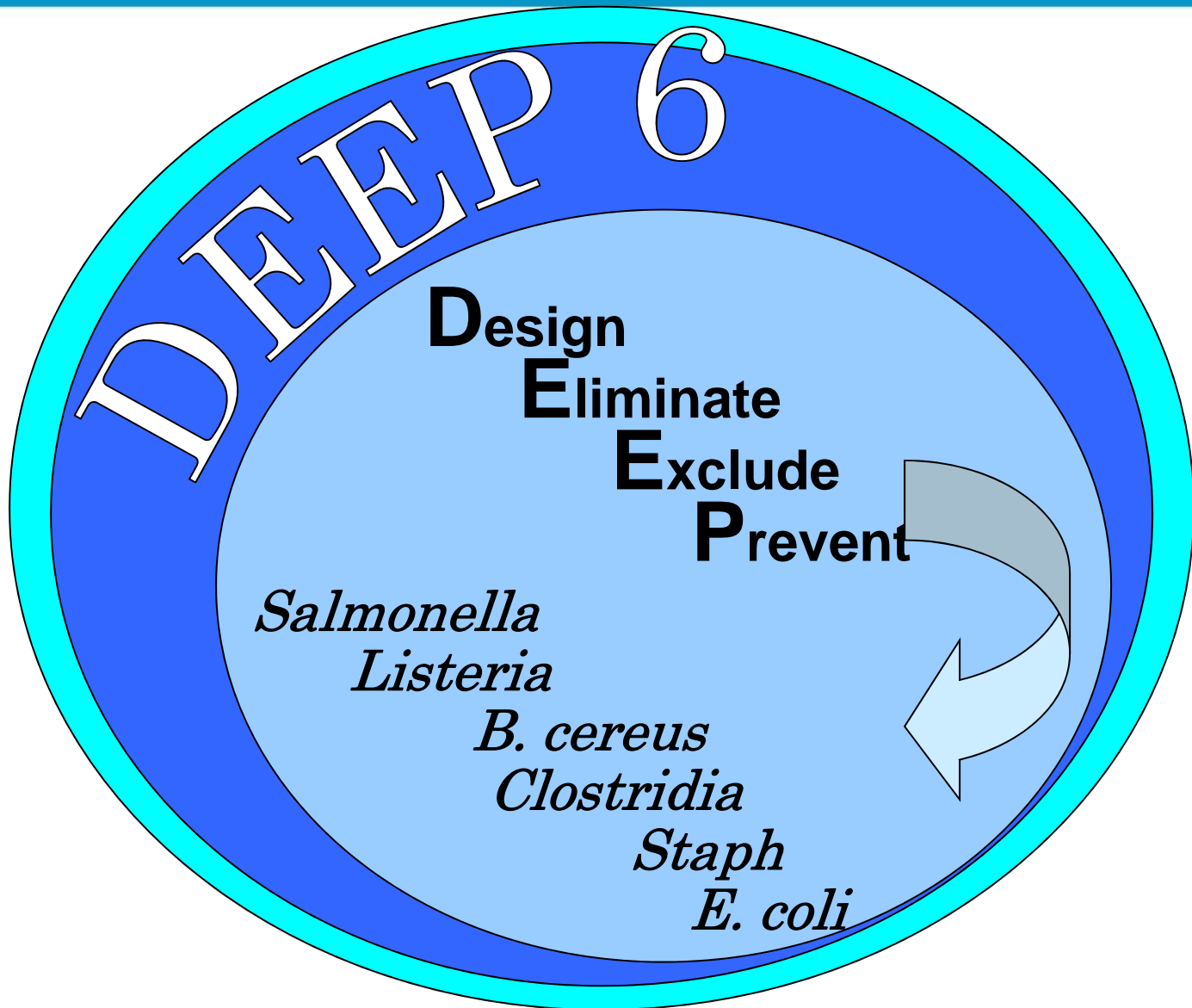
Environmental Monitoring

- Definition of a robust environmental monitoring program inconsistent many stakeholders
 - Management goal – find it or not find it
 - Frequency of testing – daily, weekly, monthly, etc.
 - Sample location(s) – varied or fixed
 - Timing – before or after sanitation cycle
 - Zone sampling considerations - focused or distributed
 - Target organism – Salmonella, Listeria
 - Reaction to findings – transient or established
 - Internal and/or external Good Laboratory Practices

GOAL: SIMPLIFY



Microorganisms of Concern & Interventions



Design



Exclude



Eliminate



Prevent



Salmonella

ILLNESS

ONSET



6 – 48 Hrs

INFECTION

D
DIARRHEA

V
VOMITING

SOURCE

GI TRACT OF ANIMALS
INCLUDING HUMANS

FACT

SURVIVES FOR YEARS
IN DRY ENVIRONMENTS

CONTROL

D
E
E
P



KILL STEP
ENVIRONMENTAL
MONITORING

#3 Risk Tolerance Differences



#3 Risk Tolerance Differences



Microbiological Control Challenges

Risk Tolerance Differences

Examples of Food Safety Risk Tolerance Differences

1. Shipping product while awaiting test results
2. Compositing 30 days of finished product samples
3. Producing product with known process control deficiencies
4. Extended production runs without clean sanitation breaks or frequent product test data

GOAL: REACH ALIGNMENT



#4 Gap in applied knowledge vs. information

Information & Materials Widely Available:

- Codex Standards
- ICMSF Book 7
- University courses and on-line material
- Expert Consultants and Seminar



Knowledge Transfer Challenges:

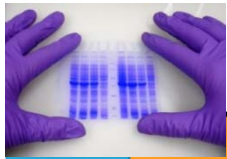
- Limited ability and resources to access information
- Training not targeted to audience need
- Experts are not best teachers
- Learn by doing & discussing vs. listening to presentations (I.e. case studies, exercise, etc)
- Communication/language differences



GOAL: LEARN FROM OTHERS

Investment in Food Safety Multifaceted

Identify What is Working and Replicate



Technology

- Surveillance
- Methods development
- Academic research
- Process Controls
- Emerging interventions



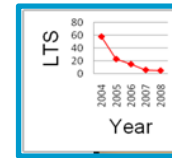
People

- Requires collaboration
- In house Technical experts
- Network of external experts
- Global resources



Training

- Needs assessment
- Standardize key contact for local delivery
- Distance learning
- Case studies & exercises



Measurement

- Audits, inspections and certification
- Cost Avoidance Measures
- Import Actions
- Consumer Contacts or reported illnesses



Summary of Insights

- Create a roadmap
- Simplify the complex, add focus
- Recognize and reconcile risk tolerance difference
- Identify and replicate when possible



BEHAVIORAL CHANGE MANAGEMENT

Elements to advance change:

- Direction and clarity
- Alignment and commitment
- Build new habits for sustainability



BEHAVIORAL CHANGE MANAGEMENT

- Provide Direction & Clarity (rational/analytic side)
 - Point to destination with specifics – change is easier when you know where you are going
 - Identify successes - investigate what is working and clone it
 - Be prescriptive around critical moves focused on specific behaviors
 - Resistance is often a lack of clarity



BEHAVIORAL CHANGE MANAGEMENT

- Motivate & align stakeholders (emotional side)
 - Knowledge does not change behavior, purpose does
 - Identify new habits and create environment to practice
 - Have patience as changing behaviors that have become automatic takes time
 - Build and enroll others through the results of others
 - What looks like laziness is often exhaustion



BEHAVIORAL CHANGE MANAGEMENT

- Shape the path, change situation
 - Stay focused on your vision
 - Tweak the environment – Clear the way to succeed
 - Simplify – Allows all to participate
 - Celebrate your success



WRITE YOUR 2012 SUCCESS STORY NOW

Results

Saved Lives
Reduced Illness

Increased Export
Resource Shift
Cost Avoidance

Preferred Status
Employer of Choice

Success Factors

Built upon
Relationships &
Existing Successes

Defined the Target
Revisited it Regularly

Patience & Flexibility
Motivate Organization

Key Learnings

Target Training to
what is needed vs.
what is available

Clarity of focus
was Key to
Success

Leverage Existing
Information

Making Change Happen

Thank you!



GENERAL MILLS



Asia-Pacific
Economic Cooperation

Contact Information

Sarah Geisert
Sr. Director Product Safety & Regulatory

General Mills
#1 General Mills Blvd. W01B
Minneapolis, MN 55426 USA
Phone: 952-474-5346
Cell: 612-845-6418
E-mail: Sarah.Geisert@Genmills.com



BACK-UP MATERIALS



Peanut Butter 2007

Specific Details

Synopsis:	Epidemiological investigation lead to direct finding of Salmonella in product. Contamination at plant by a leaky roof a likely cause.
Situation:	Epidemiology data linked multiple state illnesses to peanut butter and a specific manufacturing location. Later found by FDA to have salmonella contamination within a batch, later discovered that product had also been bulk shipped for use in ice cream
Duration of Investigation to Recall:	December 2006 epidemiology investigation begins; February 2007 recall announced.
Type of Recall:	Type I; presence of salmonella
Products Affected:	Limited to 2 firms consumer products and a small number of ice cream manufacturers.
Root Cause:	<u>Prerequisite program failure.</u> Deficiencies in facility infrastructure maintenance including leaky roof
Medical Impact of Recall:	At least 625 persons affected in 47 states, 71 hospitalizations, no deaths
Fiscal Impact of Recall:	• \$50 – 60MM estimated
Insights:	<ul style="list-style-type: none"> • Salmonella emerged as a pathogen of concern in low moisture foods. • Events happen at all size of organizations and operations. • Industry guidance quickly developed to support education and intervention efforts



Peanut Containing Products 2009

Specific Details

Synopsis:	Small, unscrupulous processor impacted over 2,800 peanut and peanut containing products and 250 brands impacted. Through an epidemiology investigation linking Salmonella illnesses in multiple state a direct link to product was established. Company went bankrupt and owner facing criminal prosecution.
Situation:	<ul style="list-style-type: none"> • Salmonella detected by a customer in a shipment of HVP for a supplier. • FDA notified via new Reportable Food Registry. • The Supplier provided HVP many manufacturers whom produced hundreds of products. • Recall announced by HVP supplier covering all production since September 2009. • FDA collected and analyzed samples at the facility and confirmed the presence of <i>Salmonella</i> Tennessee in the company's processing equipment.
Duration of recall:	January 2009 recalls began. Ultimately involved all production by supplier since Jan. 2007
Root cause:	<u>Prerequisite program failure.</u> Presence of Salmonella found in company's plant equipment, inadequate microbiological controls deficiency noted. And, intentional shipment of contaminated product identified.
Products Affected:	Over 2,800 products in US and Canada.
Medical Impact of Recall:	At least 714 people affected in 46 state and Canada. 9 reported deaths.
Financial Impact:	<ul style="list-style-type: none"> • Est. \$100 MM to industry and supplier • Firm bankrupt.
Insights:	<ul style="list-style-type: none"> • Small firm, with 1 processing plant, impacted many consumer products • Vendor selection and management programs need to emphasis • Inconsistent audit reports • Recurrence of issues remains a prevention challenge • Economically motivated actions add complexity and increase impact



Hydrolyzed Vegetable Protein 2010

Specific Details

Synopsis:	Salmonella detected by a customer in a shipment of HVP. FDA notified and begins investigation of HVP supplier. Over 150 products recalled. Recall went back to all production from September 2009. FDA indicated manufacturers with a validated “kill step” (5 log reduction) were not impacted.
Situation:	<ul style="list-style-type: none"> • Salmonella detected by a customer in a shipment of HVP for a supplier. • FDA notified via new Reportable Food Registry. • The Supplier provided HVP many manufacturers whom produced hundreds of products. • Recall announced by HVP supplier covering all production since September 2009. • FDA collected and analyzed samples at the facility and confirmed the presence of <i>Salmonella</i> Tennessee in the company’s processing equipment.
Duration of recall:	September 2009 - present
Root cause:	<u>Prerequisite program failure.</u> Presence of Salmonella found in company’s processing equipment.
Products Affected:	<ul style="list-style-type: none"> • HVP commonly ingredient used most frequently as a flavor enhancer in many processed foods, including soups, sauces, chilis, stews, hot dogs, gravies, seasoned snack foods, dips and dressings.
Medical Impact of Recall:	No illnesses reported.
Financial Impact:	<ul style="list-style-type: none"> • No estimated identified
Insights:	<ul style="list-style-type: none"> • Small firm, with 1 processing plant, impacted many consumer products • Proactive action and communication by industry to FDA may have prevented illnesses. • Products with a validated kill step (5 log) or that had a filed thermal process were not impacted. • Reconditioning of HVP allowed if process approved by FDA • How far back in time should the recall extend? What level of risk is acceptable? What about other products produced on the same line, but did not contain HVP?

