Quantifying and Communicating the Business Risks of Food Safety, Food Fraud and Food Defense

2009 Food Safety Summit
Workshop
April 27, 2009

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Agenda

- 1:00pm Welcome and Introductions
- 1:30pm Food Risks
- 2:30pm Break
- 2:45pm Case Study Example
  - Presentation of the Matrix
- 3:15pm Quantifying Food Quality and Food Safety
  - Populating the Matrix
- 3:45pm Break
- 4:00pm Quantifying Food Fraud and Food Defense
  - Populating the Matrix
- 4:30pm Enterprise Risk Management
  - Quantifying the Unknown and Unknowable
  - Next Steps
- 5:00pm Concluding Remarks & Questions

Terms

- Food Quality
- Food Safety
- Food Fraud
- Food Defense
- Food Security
- Food Adulteration
- Risk
- Risk Matrix
- Overall Food Risk Matrix

About this workshop

- Developed because of a recognized need
- Interactive- Ask questions, share experiences

Goal is to provide you with tools to succeed

B. Overview of Food Risks
(1) Food Quality and Food Safety

1:30-2:00

Quantifying and Communicating the Business Risks of Food Safety, Food Fraud and Food Defense

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Workshop

THE COST OF FAILURE

PRESENTED BY

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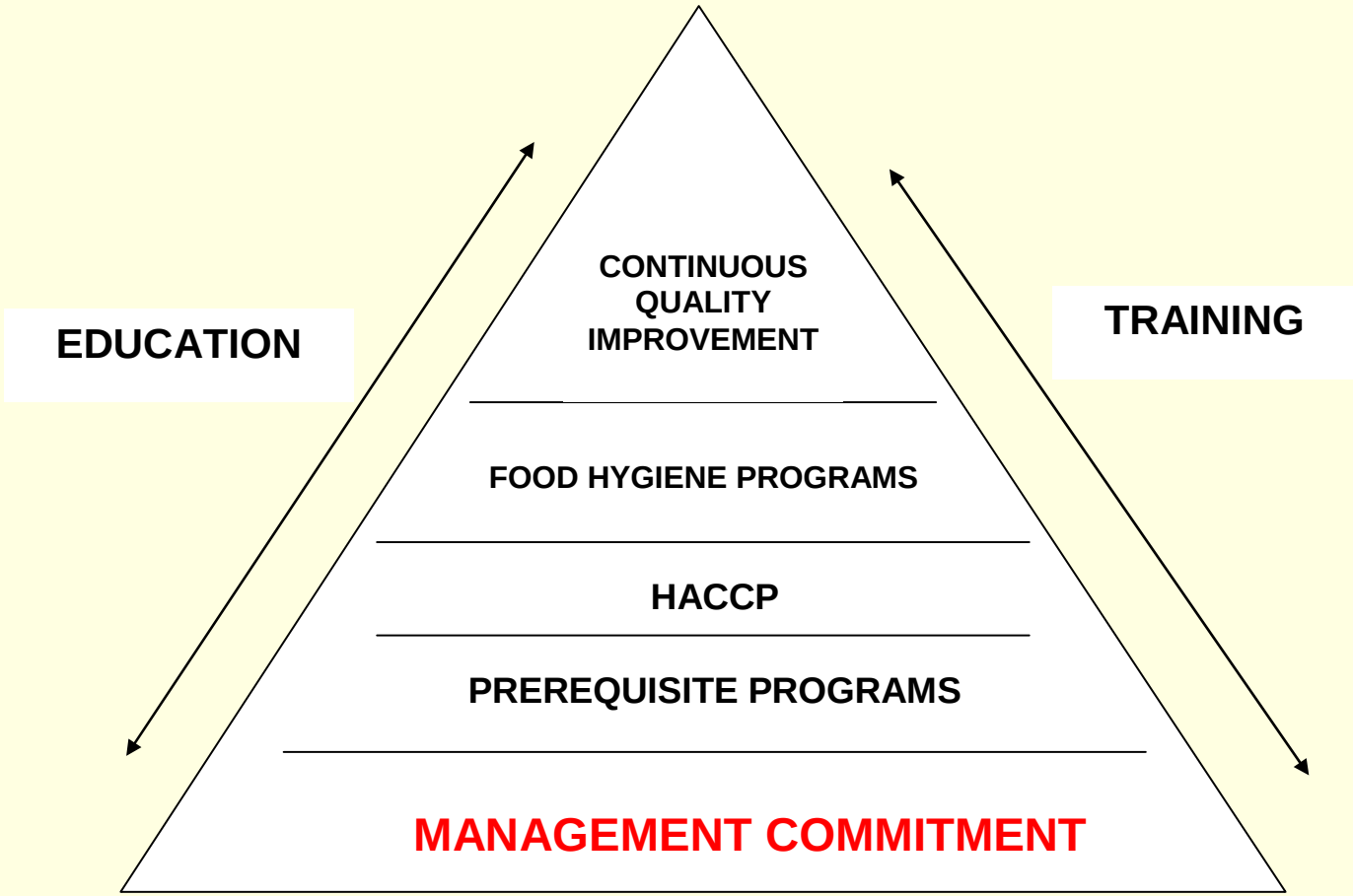
Key Question

What is the most important thing to have regarding Food Safety?

Answer

MANAGEMENT COMMITMENT

Food Safety and Quality Pyramid



Goal Of This Interactive Session

To discuss development of communication tools that a Food Safety Professional can use to obtain and maintain/sustain Management Commitment to Food Safety

Who is management?

- "C" Level
  - CEO, COO, CFO, Chief Legal Officer, Executive VP
- Next Level
  - VP Operations, VP Purchasing

Question

What is needed to get Management Commitment?

Answer

An understanding of the risks and rewards

And

The ability to effectively communicate it in terms that the C level understands

Role of Senior Management is

to Manage Risks

The Bottom Line is the Bottom Line

Often Heard Comments

- We've never had a problem before
- It's too expensive
- It's not worth the money, I'll take the chance
- No one else is doing this, it will put us at an economic disadvantage
- That's overkill

The Challenge

How do you convince someone to buy insurance in the form of a Food Safety Program?

We want to address food safety issues before the become a problem. Not during and after a crisis.

We need to develop the communications tools to overcome a lack of knowledge, apathy, smugness and denial

Recent Food Safety Issues

HAZARDS: BIOLOGICAL - CHEMICAL - PHYSICAL

BIOLOGICAL

- Ground beef - E.coli 0157:H7
- Spinach, Lettuce - E.coli 0157:H7
- Tomatoes – Salmonella
- Jalapeno Peppers - Salmonella
- Peanut Butter - Salmonella
- Cantaloupes - Salmonella
- Pot Pies - Salmonella
- Pasteurized milk – Listeria monocytogenes
- Deli Meats- Listeria monocytogenes
- Canned chili - C. botulinum
- Restaurants, cruise ships, hospitals, nursing homes, etc – Norovirus
- Restaurants and Produce (green onions) - Hepatitis A

CHEMICAL

- Pet Food - Melamine and Cyuranic acid
- Ice cream, candy, baked goods - undeclared allergens
- Melamine in dairy products from China- baby food, candy, coffee whiteners, baked goods

PHYSICAL

- Candy - metal fragments
- Baby food - plastic
- Sauces - glass

Meat recalls for E.coli 0157:H7 in 2007

POUNDS RECALLED IN 2007

- Natural State Meat Company 1/29/07 4,240 FSIS Recall - E coli
- Tyson Fresh Meats 3/2/07 16,743 FSIS Recall - E coli
- Richwood Meat Company 4/20/07 107,943 FSIS Recall - E coli
- HFX, Inc 4/20/07 259,230 FSIS Recall - E coli
- PM Beef Holdings 5/10/07 117,500 FSIS Recall - E coli
- Davis Creek Meats 5/11/07 129,000 FSIS Recall - E coli
- Tyson Fresh Meats 6/8/07 40,440 FSIS Recall - E coli
- United Food Group 6/3-6/9/07 5,700,000 FSIS Recall - E coli
- Washington Beef 7/15/07 82,286 FSIS recall - insanitary conditions
- Abbott's Meat Inc 7/21/07 26,669 FSIS Recall - E coli
- Custom Pack 7/25/07 5,920 FSIS Recall - E coli
- Interstate Meat 8/30/07 41,305 FSIS Public Health Alert - E. Coli
- Fairbank Farms 9/5/07 884 FSIS Recall - E coli
- Impero Foods 9/29/07 65 FSIS Recall - E coli
- Topps Meat Company 10/6/07 21,700,000 FSIS Recall - E coli
- Cargill 10/6/07 845,000 FSIS Recall - E coli
- J&B Meats 10/13/07 173,554 FSIS Recall - E coli
- Arko Veal Co 10/13/07 1,900 FSIS Recall - E coli
- Blue Ribbon Meats 10/24/07 8,200 FSIS Recall - E coli
- Del Mar Provision Company 10/27/07 50 FSIS Recall - E coli
- Totinos/General Mills 11/1/07 3,300,000 FSIS Recall - E coli
- Cargill 11/3/07 1,084,384 FSIS Recall - E coli
- American Foods Group 11/24/07 95,927 FSIS Recall - E coli
- Snapps Ferry 12/17/07 102 FSIS Recall - E coli
- Fresh Brands 12/27/07 14,800 FSIS Public Health Alert - E. Coli

Total amount recalled in 2007 33,756,142 pounds

Source: Marler Blog

Hepatitis A in Restaurants

- Carl's Jr. Hepatitis A Outbreak – Washington
- Chi-Chi's Hepatitis A Outbreak – Pennsylvania
- Chipotle Grill Hepatitis A - San Diego
- D'Angelo's Deli Hepatitis A Outbreak – Massachusetts
- Friendly's Hepatitis A Exposure – Massachusetts
- Houlihan's Hepatitis A Exposure – Illinois
- Maple Lawn Dairy Hepatitis A Outbreak - New York
- McDonald's Hepatitis A Outbreak – Washington
- Quizno's Hepatitis A Exposure – Massachusetts
- Soleil Produce Hepatitis A Outbreak – California
- Subway Hepatitis A Outbreak – Washington
- Taco Bell Hepatitis A Outbreak – Florida

Source: Marler Blog

Examples of Product Recall Events

Brand	Year	Problem	Bodily Injury	Recall Volume	Recall Cost	Event Implication
Perrier	1990	Excessive levels of Benzene found in bottles in US and Europe	No injuries	230,000,000 Bottles The entire worldwide inventory	$200,000,000	In 2000, revenue still 40% below that earned in 1989
Jack in the Box	1993	E.coli outbreak traced to meat from 73 restaurants	700 ill, 4 child deaths	All hamburger meat from JIB recalled	$160,000,000 Costs and reduced sales	Rehabbed the brand by getting strong food safety leadership that initiated Food Safety programs
Sudan 1	2005	Chili powder colored with illegal dye that was used to make Worcester sauce that was used in numerous products	No injuries	580 products from approx 300 producers	$360,000,000	Brand damage spread among numerous companies

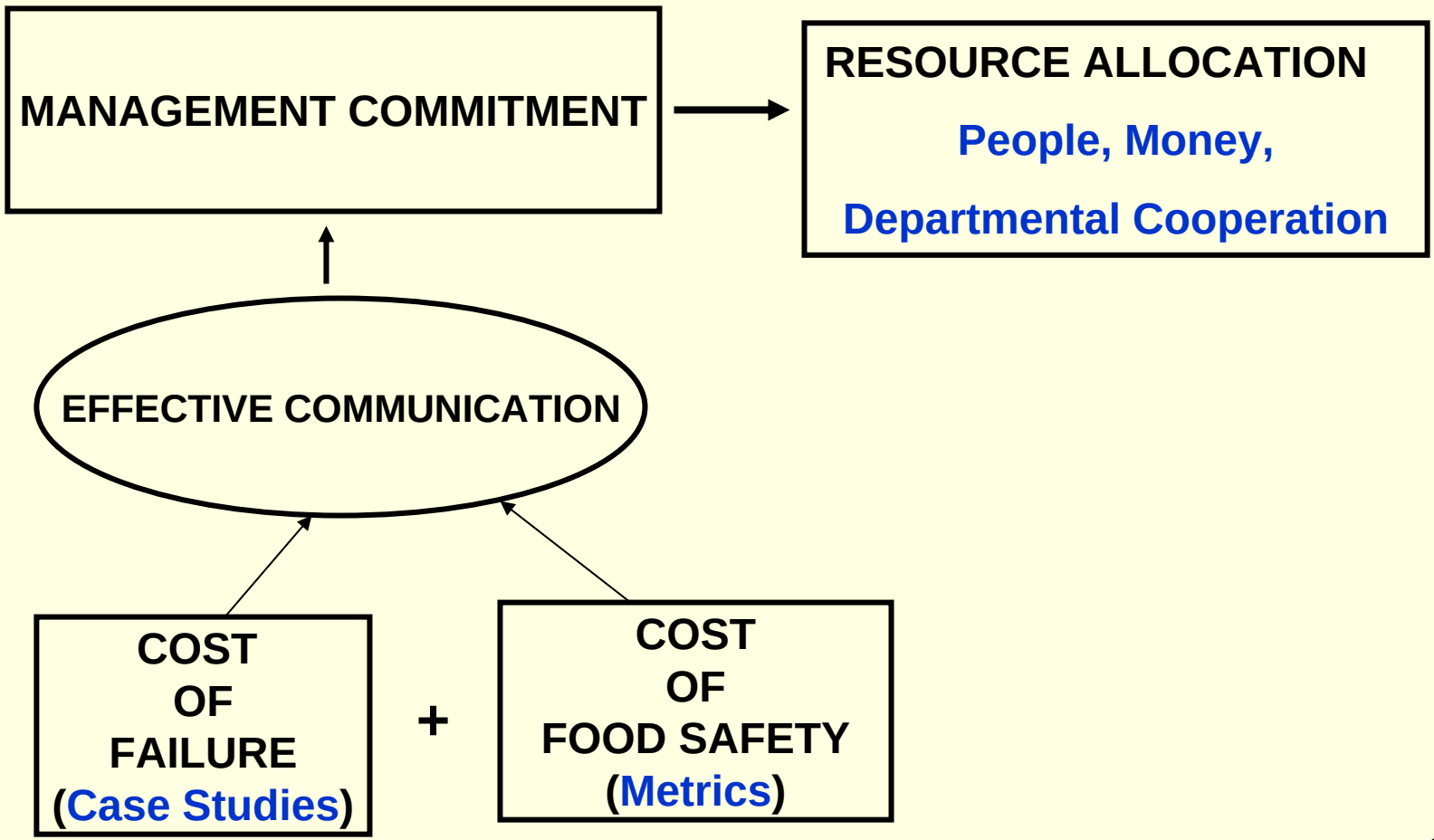
Examples of Product Recall Events

Brand	Year	Problem	Bodily Injury	Recall Volume	Recall Cost	Event Implication
Cadbury- UK	2006	Sal in Chocolate Caused by leaking drainpipe			75,000,000 Euros $105,000,000	
Snow Brands- Japan	2000	Staph in Low fat milk Poor repair to piping	15,000 ill		11,2 Billion Yen Shares fell 40% Market share went from 45% to <10%	
ConAgra Pot Pies	2007	Salmonella	272 illnesses		$30,000,000	Total review of process Redesign and instructions for microwaving
Pilgrim Pride (Wampler Food Div)	2002	Listeria in Deli Meat Never directly linked to them	8 deaths	27 Mil Pounds	$85,000,000	Went out of turkey business

Examples of Product Recall Events

Brand	Year	Problem	Bodily Injury	Recall Volume	Recall Cost	Event Implication
Maple Leaf Canada	2008	Listeria in deli meats Cause thought to be Inadequate cleaning of slicers	16-17 deaths	220 types of meat	$20,000,000	Shares driven down 28%
Peanut Corp of America (PCA)	2009	Salmonella in Peanut Butter and Peanut Pieces	9 Deaths 700+ people ill	4000+ Products	$100,000,000+	Company out of business Owner's Fate- Unknown
Odwalla	1996	E.coli 0157:H7 in unpasteurized apple juice	70 ill, 1 child died	All apple juice and other juices containing it as well as carrot juice and vegetable juice		
Chi-Chi's	2003	Hepatitis A in green onions	3 deaths 600 people ill			Company out of business

Getting Management Commitment



Explaining the Cost of Failure

Case Studies

- Cost of an everyday failure
- Cost of a major food safety crisis

Facts

- **Food Safety is a legal and moral imperative**
- **According to the CDC, 76 million cases of foodborne illnesses occur in US annually (1 in 4 people); 325,000 of these illnesses result in hospitalization; 5000 fatalities**
- **Medical costs, productivity losses, and costs of premature deaths related to the six most common foodborne illnesses (*Salmonella, Campylobacter jejuni, E.coli 0157:H7, Listeria monocytogenes, Staphylococcus aureus, Clostridium perfringens*) total approximately $6.9 Billion in losses annually.**

Product Liability Law

- **When a person is injured by a defective product that is unreasonably dangerous or unsafe, the injured person may have a claim or cause of action against the company that designed, manufactured, sold, distributed, leased, or furnished the product. In other words, the company may be liable to the person for his injuries and, as a result, may be required to pay for his damages. That, in short, is product liability; and, not surprisingly, the law that governs this kind of liability is referred to as product liability law.**

Source: Marler Clark, LLP

COST OF AN EVERYDAY FAILURE

Business Assumption

- **Food safety is more complex today than it has ever been in the past. Public health concerns of foodborne illnesses are paramount, and the costs associated could have negative impact against our company.**
- **Food safety awareness and increased expectations by our customers, clients, regulatory authority, operators and shareholders continues to be an issue of concern.**

Economic Evaluation of Food Complaint

- Medical (physician, hospitalization, medicine)
- Loss Of Productivity (days of work)
- Loss Of Sales (lack of customer trust)
- Legal Fees
- Increased Insurance Premiums
- Loss of REPUTATION !

A Real Life Example

- The Company- $2 Billion Dollars in sales
- Works on a 5% profit margin
- A food related claim can cost $75,000
- It will take $1,500,000 in sales per year to pay for this one claim
  - This may be the entire revenue for a year for one unit
- Compare this to the Cost of Food Safety activities

INFORMATION NEEDED TO DEVELOP A CASE STUDY FOR THE COST OF A MAJOR FOOD SAFETY CRISIS

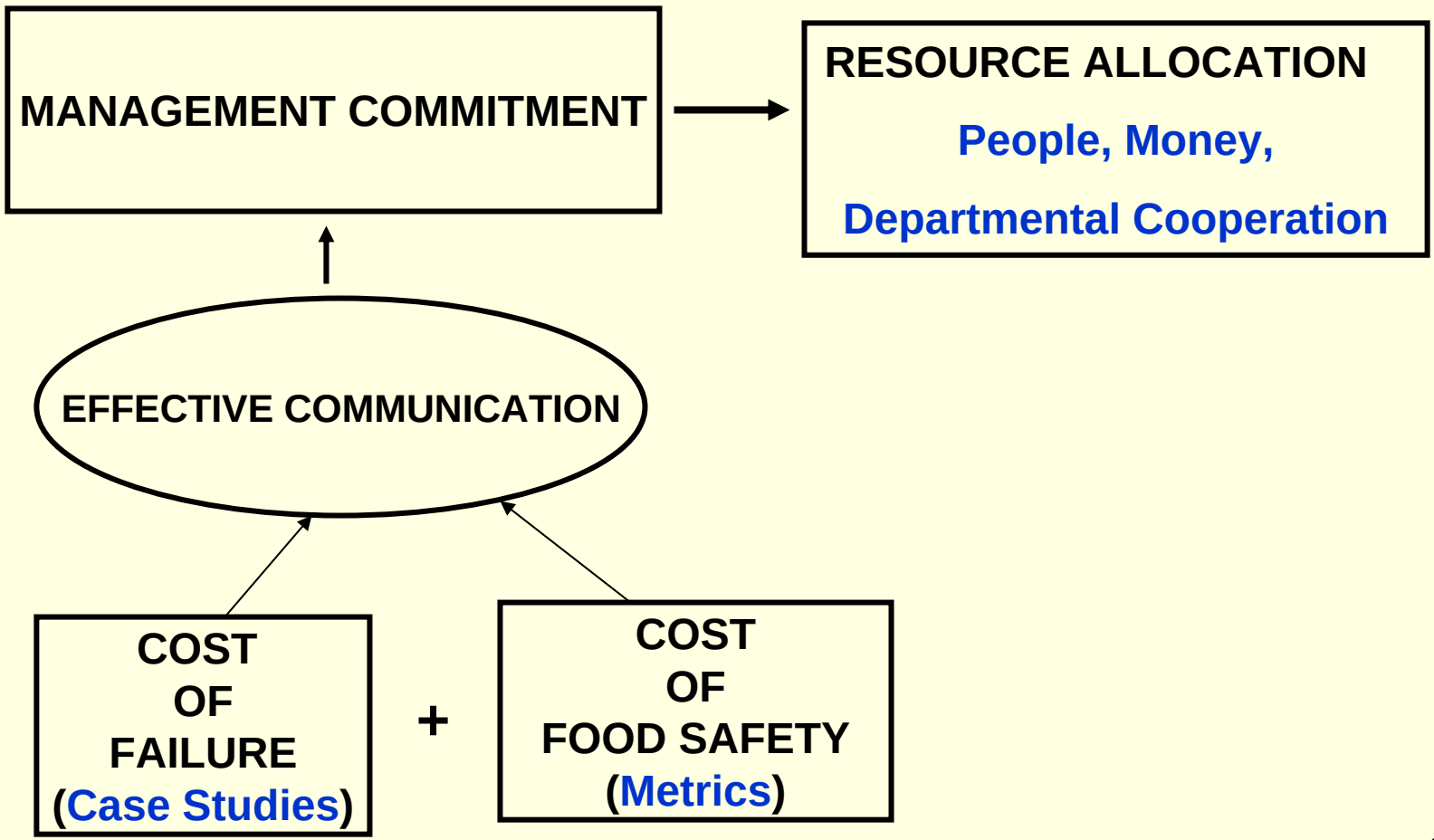
Elements To Include In Determining The Cost Of A Recall

- Product itself
- Removal of product from store (include need for secure storage space)
- Disposal of removed product
- Penalties imposed by the customer
- Replacement of product
  - Include overtime costs for all departments and any added cost for quick distribution
- Communications to inform the public
- Legal
  - Attorneys (internal and external), include experts
  - Dealing with Regulatory Agencies
  - Medical payments to individuals
  - Damages (actual and punitive)
  - Time needed for insurance audits, attorney audits, education
  - Additional requests for liability insurance, indemnification agreements
- Time spent on the recall by company personnel (include overtime costs)
- Use of temporary personnel
- Investigation of cause of the problem
- Business interruption

Elements To Include In Determining The Cost Of A Recall (Con't)

- Sales lost by supplier
- Sales lost by customer
- Space lost to a competitor
- Loss of market share
- Time not spent on the rest of the business
- Reduced demand for this type of product (from this company and in the category)
- Impact on international trade
- Loss of value of company stock
- Increased insurance costs
- Advertising for customers and consumers
- Travel costs (troubleshooting, to see customers)
- Office expenses for communications (reproduction, FedEx, couriers, printing, telephones, etc)
- Public Relations
- Good will
- Changes to facility, product, process, packaging, QA programs, training, increase in testing
- Morale of all stakeholders (attitudes and motivation)

Getting Management Commitment



COST OF FOOD SAFETY

Top 10 QA Questions

From a presentation by Frank Ferko, Director, Distribution-FSQA US Foodservice to the NRA QA Group

1. **What were the Total Restaurant Operations Revenues/Sales last year at your company?**

2. **What was the Earnings per Share (EPS) last year at your company?**

3. **What was the Net Profit last year for your company?**

4. **What was the cost of the Quality Assurance Department last year at your Company (salary, benefits and expenses)?**

5. **What was the amount of money the Quality Assurance Department saved your Company last year? (Includes but is not limited to, for example, credits from vendors, prevention of failures (if measurable), restaurant operations (if somehow you kept a restaurant open), and improved food or labor cost.)**

Top 10 QA Questions (Con't)

6. **Who is your QA Department's financial advisor at the Company? You may have a Business Manager. Is this if within your department or do you share with others? If you don't have one you should try to get one.**

7. **Who makes the final decision about the QA Department's budget in your Company**

8. **How much was spent on QA per $1,000,000 of sales?**

9. **How many steps up the ladder from the top is the QA person to the CEO? (Example: Senior Director QA then VP Administration then President then CEO = 3)**

10. **How much more than what you listed in #4 above do you need to do your job in QA**

A CEO's Checklist From A Lawyer's Perspective

- Put qualified people in charge of food safety
- Listen to the qualified food safety professionals you've hired
- Use contracts with your vendors to protect your customers and indemnify your company of liability if something goes wrong
- Understand why information management (IT) is important to your company, especially as it relates to the food safety mission
  - "Usability Factor"
- Stay current with regulatory and code compliance for every jurisdiction in which your company operates

From: Marler, William, article in Food Safety Magazine, October/November 2007, "Food Safety & the CEO"

To Do's

- Gather information and develop appropriate case studies as communication tools
- Understand what Food Safety costs the company
- Develop metrics that show the value of Food Safety to the company
  - Don't forget consistent product quality, lower operating costs, less waste

Questions- Contact me

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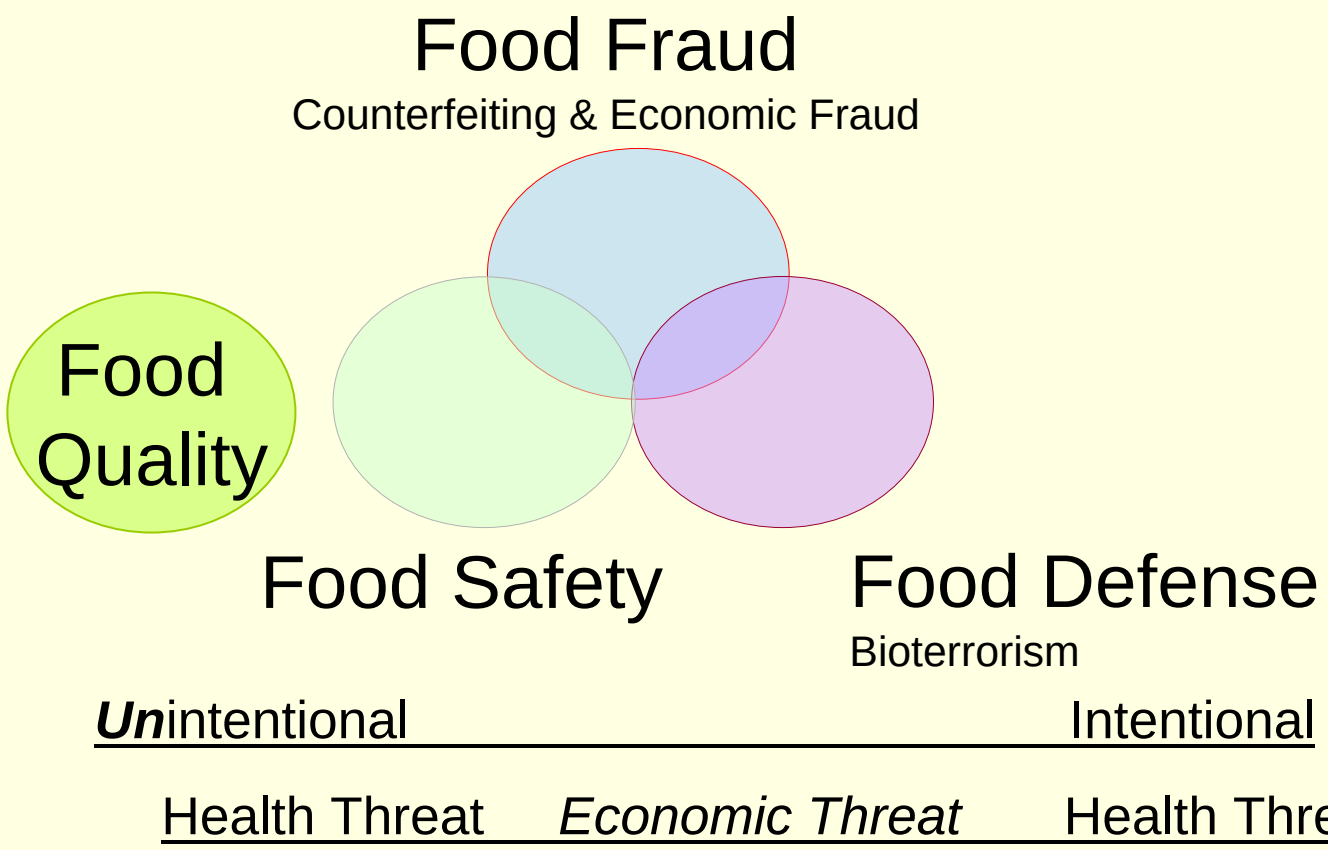
B. Overview
(2) Food Fraud and Food Defense

2:00-2:30

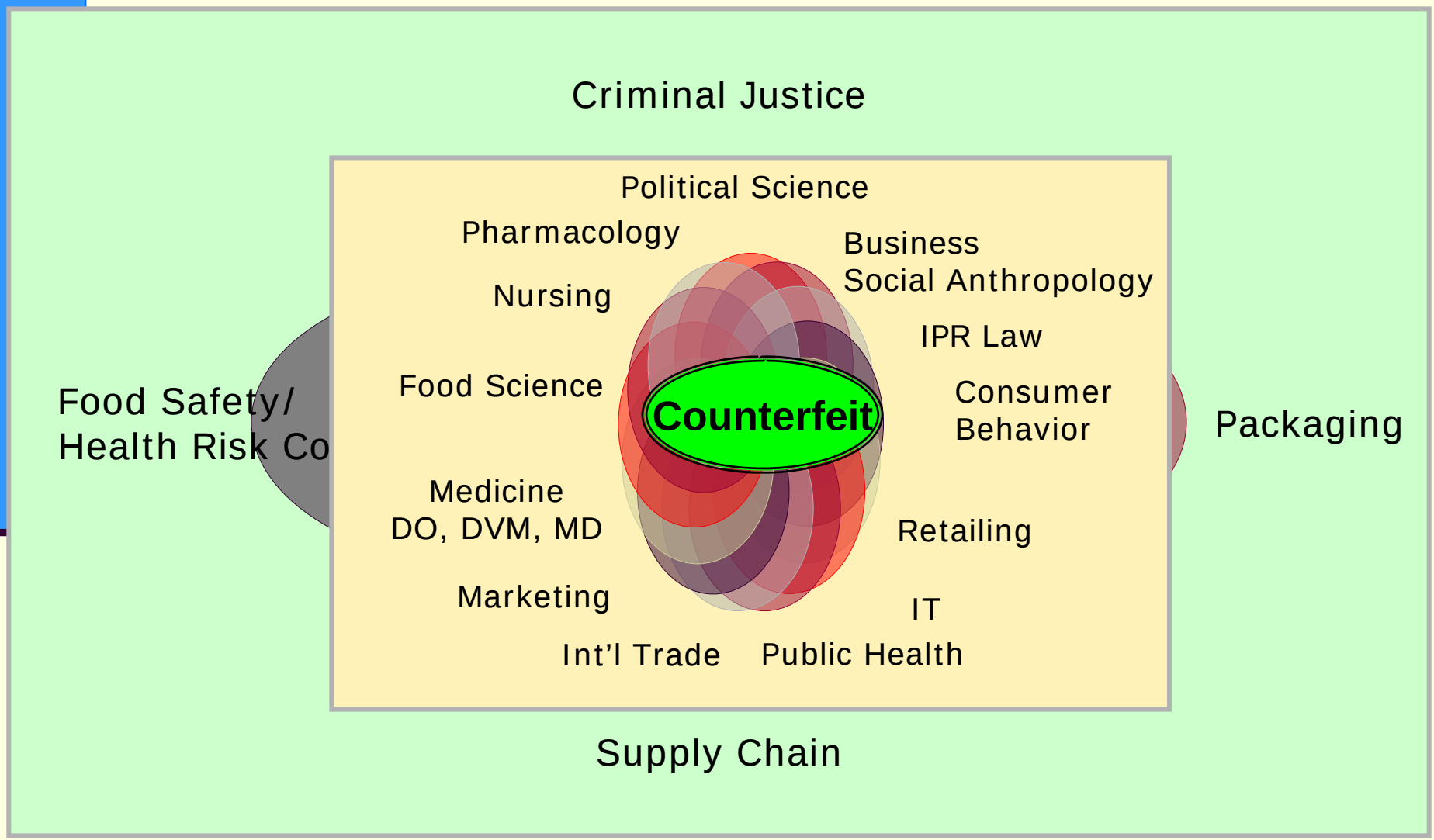
B. Overview
(2) Food Fraud and Food Defense
Overview: The Food Continuum



The Result: Adulteration

- The ***effect*** of a public health threat is ***Food Adulteration.***
- The ***cause*** could be from a unique set of root factors.
- Understanding the nature of the root factors is critical to efficient and effective detection and deterrence.

B. Overview
(2) Food Fraud and Food Defense
Overview: Extremely Interdisciplinary



Food Fraud: Types of Fraud

- Asset misappropriation
  - embezzlement/ deception by employees
- Accounting fraud
- Corruption and bribery
  - racketeering and extortion
- Money laundering
- IP infringement
  - trademarks, patents, counterfeit products and services, industrial espionage

(PriceWaterhouseCoopers, 2007)

Food Fraud: Counterfeiting

- The FBI: "…the crime of the 21st century"
- The COE: "…a silent pandemic"
- The World Customs Organization (WCO) estimates that counterfeiting was a $512 billion market in 2004, up 100 times over the previous twenty-years, which equates to 5-7% of global trade.
- In addition, only 5-10% is in what would be considered "luxury" goods.
- 1-3% of the *US* Drug Supply…
- The global counterfeit food threat is ~$49 billion, and the UK's Food Standards Board (FSA) estimates the UK "level of fraud" around 10%.

Food Fraud: Types of Counterfeiting

- Adulterator
- Tamperer
- Over-runs
  - Licensee-Fraud
  - Re-Manufacturing
  - Unauthorized Refill
- Thief
- Diversion
  - Smuggling
  - Parallel Trade
  - Origin Laundering
- Simulation
- Counterfeiter

B. Overview
(2) Food Fraud and Food Defense
Types and Scope of Food Fraud

- Product Substitution
- Product Up-labeling
- Product Adulteration
- Product Copy/ Unauthorized Refill
- Product "Freshening"
- Allergens
- Pathogens
- Poison or Harmful Chemicals
- Inactive Ingredients or Preservatives
- Other Non-GMP Environment Issues
- RECALL!!!!!

Types and Scope of Food Fraud -- Examples

- Conventional sold as organic
- Pet food with melamine
- Catfish with banned antibiotics
- Sudan Red Carcinogen Colorant
- Scallops with bacteria
- Toothpaste with diethylene glycol
- Species swapping – Grouper, etc.
- Methanol in Alcohol
- Low Nutritional Content in Infant Formula
- Cases of Red Bull energy drink

"The Business Case Analysis for Anti-Counterfeit Food Research," Spink & Mace, Food Safety Policy Center, MSU, 2007

- counterfeit food is a public health threat;
- as is done in Food Safety and Food Security, the most efficient and effective implementation is incorporating anti-counterfeit strategic steps into current "Standard Operating Procedures" (HACCP, GMP, Six Sigma, QA, etc.);
- current anti-counterfeit strategies and procedures from elsewhere in industry will be efficient and effective for the food industry; and
- the range of criminals and the range of actions will continue to be more aggressive, bolder, and more effective at infiltrating the legitimate food supply chain.

Food Defense Overview

- Food Defense
  - *Food defense* is the collective term used by the FDA, USDA, DHS, etc. to encompass activities associated with protecting the nation's food supply from ***terrorist activities***. This term encompasses other similar verbiage (i.e., bioterrorism (BT), counter-terrorism (CT), etc.) (Source: FDA/CFSAN)
- Risk Assessment
  - "Simple Models": great uncertainty and variability, use many assumptions, usually only valid against known scenarios, and apply to apply to very general (non-specific) targets.

Food Defense Initiatives

- DHS National Infrastructure Protection Plan
- FDA Food Protection Plan
- Carver plus Shock
- Strategic Partnership Program on Agroterrorism (SPPA)
- Raise Awareness
  - ALERT, SMART, etc

B. Overview
(2) Food Fraud and Food Defense
Carver+Shock Tool

- Expand on risk-based decision making and the operational risk management principles
- Software based system using a user driven survey
- Carver+Shock to identify food defense/ attack vulnerabilities, bioterrorism focused
- Breaks risks to small steps (nodes) farm-to-fork
- Expands on the “Carver” is US Military vulnerability tool
- Free, public access to the software at:
  - http://www.cfsan.fda.gov/~dms/carver.html

B. Overview
(2) Food Fraud and Food Defense
Carver+Shock

- CARVER is an acronym for the following six attributes used to evaluate the attractiveness of a target for attack:
  - **C -** Criticality
  - **A -** Accessibility
  - **R -** Recuperability
  - **V -** Vulnerability
  - **E -** Effect
  - **R -** Recognizability
    + Plus
  - **Shock**

B. Overview
(2) Food Fraud and Food Defense
Carver+Shock

Shock Scale	
Target has major historical, cultural, religious, or other symbolic importance. ▪ Loss of over 10,000 lives. Major impact on sensitive subpopulations, e.g., children or elderly. National economic impact more than $100 billion.	9-10
Target has high historical, cultural, religious, or other symbolic importance	7-8
Target has moderate historical, cultural, religious, or other symbolic importance.	5-6
Target has little historical, cultural, religious, or other symbolic importance	3-4
Target has no historical, cultural, religious, or other symbolic importance. ▪ Loss of life less than 10. No impact on sensitive subpopulations, e.g., children or elderly. National economic impact less than $100 million	1-2

B. Overview
(2) Food Fraud and Food Defense
>>Title FD5Carver+Shock Screens

- Step 1 – Establishing Parameters
- Step 2 – Assembling Experts
- Step 3 – Detailing Food Supply Chain
- Step 4 – Assigning Scores
- Step 5 – Applying What Has Been Learned

FDA Food Protection Plan – Scope of Risk

- Prevention
  - Increasing corporate responsibility to prevent food-borne illnesses
  - Identifying food vulnerabilities and assess risks
  - Expanding the understanding and use of effective mitigation measures
- Intervention
  - Focus inspections and sampling based on risk
  - Enhance risk-based surveillance
  - Improve the detection of food system “signals” that indicate contamination
- Response
  - Improve immediate response
  - Improve risk communications to the public, industry and other stakeholders

(FDA Food Protection Plan, Fact Sheet, 2008)

Final Consideration

- Monitoring all imported product is not practical.
- Monitoring all international food manufacturing is not practical.
- Focus on the root of the risk and actions…
  - ***"the Chemistry of the Crime":*** Criminal, Opportunity, and Victim
- The Strategy
  - Intelligence Gathering
  - Create a Forum
  - Create a Awareness/ Harmonization

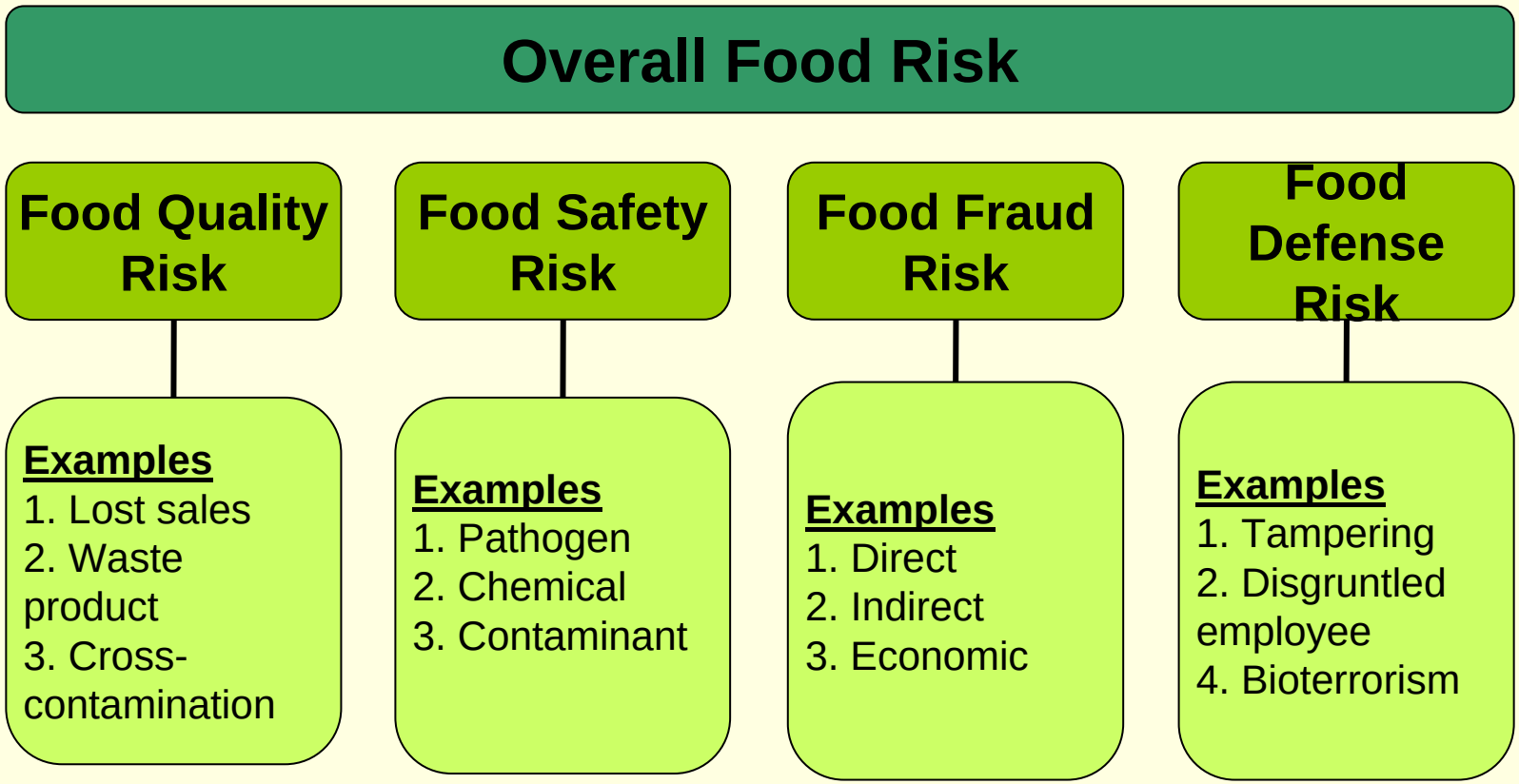
Break

2:30-2:45

B. Overview
(3) Case Study Example

2:45-3:15

B. Overview
(3) Case Study Example
The Four Cornerstones of Food Risk



B. Overview
(3) Case Study Example
Overall Food Risk

- The final output is a quantification of the food related risks of: food quality, food safety, food fraud, and food defense.

Overall Food Risk	Total Severity Risk ($)		Total Probability Risk (%)		Weighted Risk ($)
Food Quality	$ 299,000	x	93%	=	$ 284,010
Food Safety	$ 500,000	x	62%	=	$ 311,250
Food Fraud	$ 5,555,000	x	75%	=	$ 4,166,250
Food Defense	$ 36,000,000	x	26%	=	$ 5,260,000
OVERALL FOOD RISK	$ 42,354,000	x	64%	=	$ 10,021,510
Risk Assessment Position					
Acceptable/ Borderline/ Unacceptable/ Catastrophic					

Goal and Objective

- This is a process to correlate all food risks into a structure that can be incorporated into Enterprise Risk Management (etc.)
- The process is clearly defined and transparent.

Goal: Correlate food related risks with overall corporate risks, to support expenditures to mitigate the risks.
Objective: Build a system to identify, and through interdepartmental collaboration, quantify the risks.

B. Overview
(3) Case Study Example
Identify Product

- The first step is to define the details of what is being analyzed. The descriptors can be changed in any way that fits the product/company.

Product:	E.g. Pears, Organic, Bartlett
Product $/lb:	E.g. $1.99/lb
Volume $/yr:	E.g. $1,000,000
Channel:	E.g. Mass/ Grocery/ Specialty
Other1:	E.g. Company/ shipping carrier/ source
Other2:	E.g. Brand/ company/ Mfg Plant/ etc.

I. Food Quality

	Examples
A - Biological	Slime
B - Physical	Bruises
C - Chemical	Excess wax
D - Other	Mis-labeled sku#

II. Food Safety

	Examples
A - Biological	Salmonella
B - Physical	Wood shards, rocks
C - Chemical	Pesticides

III. Food Fraud

	Examples
A - Direct Health Threat	Melamine in Pet Food
B - Indirect Health Threat	Tamper Date Codes
C - Economic Threat Only	Uplabeling
D - Other	Tax Avoidance Smuggling

IV. Food Defense

	Examples
A - Biological	Spray, in store
B - Physical	Pins, in store tamper
C - Chemical	Spray, in store
D - Insurance Premium	Insurance Premium

- First, fill in the risks and examples for this product/detail:
  - Food Quality
  - Food Safety
  - Food Fraud
  - Food Defense

I. Food Quality

	Examples	Event Reaction	Total Risk Type of Cost
A - Biological	Slime	Dispose	Throw Out
B - Physical	Bruises	Dispose	Throw Out
C - Chemical	Excess wax	Dispose	Throw Out
D - Other	Mis-labeled sku#	None	Lost Revenue

II. Food Safety

	Examples	Event Reaction	Total Risk
A - Biological	Salmonella	Recall, Class I	
B - Physical	Wood shards, rocks	Recall, Class I	
C - Chemical	Pesticides	Recall, Class II	

III. Food Fraud

	Examples	Event Reaction	Total Risk
A - Direct Health Threat	Melamine in Pet Food	Recall, Class I	Lost Revenue
B - Indirect Health Threat	Tamper Date Codes	Recall, non-Class	Lost Revenue
C - Economic Threat Only	Uplabeling	Recall, Class III	TBD
D - Other	Tax Avoidance Smuggling	TBD, Tangent Risk	TBD

IV. Food Defense

	Examples	Event Reaction	Total Risk
A - Biological	Spray, in store	Recall, Class I	Civil Liability
B - Physical	Pins, in store tamper	Recall, Class I	Civil Liability
C - Chemical	Spray, in store	Recall, Class I	Civil Liability
D - Insurance Premium	Insurance Premium	Pay	Cost

- Next, Fill in the Event Reaction and Type of Cost

I. Food Quality					Total Risk Severity ($)		Total Risk Probability ($/1 yr)
			Total Risk		$ 299,000	x	93%
	Examples	Event Reaction	Type of Cost				*1,25,50,75,99%*
A - Biological	Slime	Dispose	Throw Out		$ 124,000	x	99%
B - Physical	Bruises	Dispose	Throw Out		$ 100,000	x	99%
C - Chemical	Excess wax	Dispose	Throw Out		$ 25,000	x	99%
D - Other	Mis-labeled sku#	None	Lost Revenu		$ 50,000	x	75%

II. Food Safety					Total Risk Severity ($)		Total Risk Probability ($/1yr)
			Total Risk		$ 375,000	x	50%
	Examples	Event Reaction					*1,25,50,75,99%*
A - Biological	Salmonella	Recall, Class I			$ 125,000	x	99%
B - Physical	Wood shards, rocks	Recall, Class I			$ 125,000	x	50%
C - Chemical	Pesticides	Recall, Class II			$ 125,000	x	50%

III.

A
B
C
D

IV.

A							
B - Physical	Pins, in store tamper	Recall, Class I	Civil Liability		$ 1,000,000	x	1%
C - Chemical	Spray, in store	Recall, Class I	Civil Liability		$ 15,000,000	x	1%
D - Insurance Premium	Insurance Premium	Pay	Cost		$ 5,000,000	x	99%

Next:

- for ***Food Quality*** and ***Food Safety***
- Fill in the Severity and Probability
- Per event or per one year

Next:

- for ***Food Fraud*** and ***Food Defense***
- Fill in the Severity and Probability
- Per event or per 10 years

B - Physical	Wood shards, rocks	Recall, Class I		$ 125,000	x	50%
C - Chemical	Pesticides	Recall, Class II		$ 125,000	x	50%
III. Food Fraud				Cost Per Event ($, or over 10 yrs)		Total Risk Probability ($/10yr)
			Total Risk	$ 5,555,000	x	75%
	Examples	Event Reaction				*1,25,50,75,99%*
A - Direct Health Threat	Melamine in Pet Food	Recall, Class I	Lost Revenue	$ 5,000,000	x	75%
B - Indirect Health Threat	Tamper Date Codes	Recall, non-Class	Lost Revenue	$ 500,000	x	75%
C - Economic Threat Only	Uplabeling	Recall, Class III	TBD	$ 50,000	x	75%
D - Other	Tax Avoidance Smuggling	TBD, Tangent Risk	TBD	$ 5,000	x	75%
IV. Food Defense				Cost Per Event ($, or over 10 yrs)		Total Risk Probability ($/10yr)
			Total Risk	$ 36,000,000	x	26%
	Examples	Event Reaction				*1,25,50,75,99%*
A - Biological	Spray, in store	Recall, Class I	Civil Liability	$ 15,000,000	x	1%
B - Physical	Pins, in store tamper	Recall, Class I	Civil Liability	$ 1,000,000	x	1%
C - Chemical	Spray, in store	Recall, Class I	Civil Liability	$ 15,000,000	x	1%
D - Insurance Premium	Insurance Premium	Pay	Cost	$ 5,000,000	x	99%

The Overall Food Risk

I. Food Quality				Total Risk Severity ($)		Total Risk Probability ($/1 yr)		Weighted Risk ($)
			Total Risk	$ 299,000	x	93%	=	$ 284,010
	Examples	Event Reaction	Type of Cost			*1,25,50,75,99%*		
A - Biological	Slime	Dispose	Throw Out	$ 124,000	x	99%	=	$ 122,760
B - Physical	Bruises	Dispose	Throw Out	$ 100,000	x	99%	=	$ 99,000
C - Chemical	Excess wax	Dispose	Throw Out	$ 25,000	x	99%	=	$ 24,750
D - Other	Mis-labeled sku#	None	Lost Revenue	$ 50,000	x	75%	=	$ 37,500

II. Food Safety				Total Risk Severity ($)		Total Risk Probability ($/1yr)		Weighted Risk ($)
			Total Risk	$ 375,000	x	50%	=	$ 248,750
	Examples	Event Reaction				*1,25,50,75,99%*		
A - Biological	Salmonella	Recall, Class I		$ 125,000	x	99%	=	$ 123,750
B - Physical	Wood shards, rocks	Recall, Class I		$ 125,000	x	50%	=	$ 62,500
C - Chemical	Pesticides	Recall, Class II		$ 125,000	x	50%	=	$ 62,500

III. Food Fraud				Cost Per Event ($, or over 10 yrs)		Total Risk Probability ($/10yr)		Weighted Risk ($)
			Total Risk	$ 5,555,000	x	75%	=	$ 4,166,250
	Examples	Event Reaction				*1,25,50,75,99%*		
A - Direct Health Threat	Melamine in Pet Food	Recall, Class I	Lost Revenue	$ 5,000,000	x	75%	=	$ 3,750,000
B - Indirect Health Threat	Tamper Date Codes	Recall, non-Class	Lost Revenue	$ 500,000	x	75%	=	$ 375,000
C - Economic Threat Only	Uplabeling	Recall, Class III	TBD	$ 50,000	x	75%	=	$ 37,500
D - Other	Tax Avoidance Smuggling	TBD, Tangent Risk	TBD	$ 5,000	x	75%	=	$ 3,750

IV. Food Defense				Cost Per Event ($, or over 10 yrs)		Total Risk Probability ($/10yr)		Weighted Risk ($)
			Total Risk	$ 36,000,000	x	26%	=	$ 5,260,000
	Examples	Event Reaction				*1,25,50,75,99%*		
A - Biological	Spray, in store	Recall, Class I	Civil Liability	$ 15,000,000	x	1%	=	$ 150,000
B - Physical	Pins, in store tamper	Recall, Class I	Civil Liability	$ 1,000,000	x	1%	=	$ 10,000
C - Chemical	Spray, in store	Recall, Class I	Civil Liability	$ 15,000,000	x	1%	=	$ 150,000
D - Insurance Premium	Insurance Premium	Pay	Cost	$ 5,000,000	x	99%	=	$ 4,950,000

Summary: The Overall Food Risk

- Overall Food Risk is summarized in the table
- The level of detail is defined by the development time allotted, history, and expert panel opinion

Overall Food Risk	Total Severity Risk ($)		Total Probability Risk (%)		Weighted Risk ($)
Food Quality	$ 299,000	x	93%	=	$ 284,010
Food Safety	$ 500,000	x	62%	=	$ 311,250
Food Fraud	$ 5,555,000	x	75%	=	$ 4,166,250
Food Defense	$ 36,000,000	x	26%	=	$ 5,260,000
OVERALL FOOD RISK	$ 42,354,000	x	64%	=	$ 10,021,510

Risk Assessment Position
Acceptable/ Borderline/ Unacceptable/ Catastrophic

C. Food Factors
(1) Food Quality

3:15pm

C. Food Factors
(1) Food Quality
Is

- Food Quality is a statement of the status of the product and package, in relations to “salability”.
  - **Act:** Unintentional/No Health Threat
  - **Modes Operandi**: Response
  - **Impact:** Consumer satisfaction, lost sales, spoiled product

C. Food Factors
(1) Food Quality
Trend

- The consumer focus on nutritious and fresh food has led to an increase in the number and volume of products at retail.
  - Increased demand for a wider variety of product, year-round, has expanded the global supply chain.
  - A consumer focus on nutrition has led to an increase in scrutiny of presentation
  - Product is in transit and on the shelf longer.

C. Food Factors
(1) Food Quality
Component 1 - Pathogen

- Pathogens, and more specifically biological factors, include components that lead to spoilage or other un-salable conditions.

C. Food Factors
(1) Food Quality
Component 2 – Physical/ Handling

- This includes all physical contaminants or handling of the product.
  - Contaminants could be excessive stem or leaves, dust from excessive static electricity, or even suspect water spots.
  - Bruises or damage from rough handling in-manufacturing, in-transit, or in-store
  - Shoddy packaging or other attributes such as dirty pallets, can render a product unsalable through ineffective merchandising

C. Food Factors
(1) Food Quality
Component 3 - Chemical

- Includes agriculture, processing, or environmental contaminants that lead to un-salable conditions.
  - Excess wax, packaging residue or scraps, off-gassing of other foods, environmental foul smells, etc.

C. Food Factors
(1) Food Quality
Component 4 – Other

- The fourth “contaminant” is included for emerging risks. It is important to maintain vigilant and diligent monitoring of new threats.

C. Food Factors
(1) Food Quality
Risk

- The risk is unsalable product that is not returnable, and thus, is beyond lost profit to lost revenue.

C. Food Factors
(1) Food Quality
Discussion/ Enter Data

- Consumer focus on safe and nutritious fresh food, and more focus on aesthetics.
  - Longer supply chains, year-round
- ***Action: Enter Data***

C. Food Factors
(2) Food Safety

3:30pm

C. Food Factors
(2) Food Safety
Is

- Food Safety is a statement of the status of the product and package, in relation to being safe for immediate and future human consumption.
  - **Act:** Unintentional/Health Threat
  - **Modes Operandi:** Replication
  - **Impact:** Recall, legal liability, lost sales

C. Food Factors
(2) Food Safety
Trend

- The increased awareness of the lack of total traceability leads to consumer pressure for more supply chain visibility is combined with the increased ability to precisely trace outbreaks to specific companies and individuals.
  - Wide distribution and fewer suppliers lead to broader impacts of one event
  - Increased traceability leads to the ability to identify the source of contamination

C. Food Factors
(2) Food Safety
Component 1 - Pathogen

- This includes pathogen, and all biological, contaminants which are now on the consumer radar.
  - Precise DNA identification of source
  - Consumer automatic reaction to recalls

C. Food Factors
(2) Food Safety
Component 2 – Physical/ Handling

- This is focused on physical contaminants or handling that leads to a public health risk.
  - Manufacturing or processing contaminants
  - Physical handling that leads to an unsafe risk danger

C. Food Factors
(2) Food Safety
Component 3 - Chemical

- Chemical contaminant arise from the environment, manufacturing, food, or packaging.
  - Environmental or manufacturing contaminants
  - The food, itself, including pesticide residue
  - Packaging material migration includes residue, environmental contaminants, or additives

C. Food Factors
(2) Food Safety
Contaminant 4 - Other

- The fourth “contaminant” is included for emerging risks. It is important to maintain vigilant and diligent monitoring of new threats.
- For Food Safety, HACCP covers the first three contaminants. Other contaminants either fall into a previous contaminant or a different factor (FQ, FF, or FD).

C. Food Factors
(2) Food Safety
Risk

- The risk is a public health threat that could lead to a recall or legal liability, and associated costs.
  - Recalls : Class I, II, & III
  - Disposal
  - Recovery

C. Food Factors
(2) Food Safety
Discussion/ Enter Data

- A prevention/ detection/ Recovery plan:
  - Prevention is the most economical action. The challenge is focusing on effective countermeasures.
  - Detection and monitoring is key to identify and measure the unexpected events
  - A recovery and communication plan is critical to mitigate risk and reduce lost revenue.
- ***Action: Enter Data***

Break

3:45-4:00pm

C. Food Factors
(3) Food Fraud

4:00pm

C. Food Factors
(3) Food Fraud
Is

- This is the intentional adulteration of food but with no intent for a public health threat
  - **Act:** Intentional/Economic
  - **Modes Operandi:** ***Profit***
  - **Impact:** A public health threat could lead to a Class I recall (e.g. Melamine). Economic threats cause could undermine consumer trust. The potential public health threat through negligence, not intent.

C. Food Factors
(3) Food Fraud
Trend

- This unique factor is gaining in recognition by industry and by agencies. e.g. 5/1/09 FDA Meeting on Economic Motivated Adulteration
  - A wide range of fraudulent activities are being classified and grouped for analysis and for detection and deterrence (prevention).
  - ***"The Chemistry of the Crime"*** is being recognized as a legitimate research discipline
  - Tip: Include in HACCP… just emerging

C. Food Factors
(3) Food Fraud
Component 1 – Direct Threat

- This includes an adulterant that causes a public health threat.
  - Melamine as a ‘counterfeit additive’
  - Diethylene Glycol in cough syrup versus toothpaste
  - Beyond “profit”, understand the root motivation for the action.

C. Food Factors
(3) Food Fraud
Component 2 – Indirect Health Threat

- In this case, the public health threat is delayed or a function of bio-accumulation.
  - Tampering of date codes, could lead to reduced nutritional content or reduced preservatives
  - Pesticide residues could bio-accumulate in the consumer
  - Undeclared residual or packaging volatiles

C. Food Factors
(3) Food Fraud
Component 3 – Economic Threat Only

- In this case, the threat is purely economic.
  - Label Fraud, trademark violation, amount/ concentration, country of origin labeling fraud
  - Credence attribute fraud, such as “fair trade”
  - Tax avoidance smuggling or schemes

C. Food Factors
(3) Food Fraud
Contaminant 4 - Other

- The fourth “contaminant” is included for emerging risks. It is important to maintain vigilant and diligent monitoring of new threats.
  - Where is there currently an economic opportunity
  - What new types of threats are in other industries
  - What product or production changes create new opportunities (gaps or risk exposure)

C. Food Factors
(3) Food Fraud
Risk

- The risk is a public health threat, but also other recalls or legal liability, and the associated costs. Also, loss of sales and loss of brand equity.
  - Recalls: Class I, II, & III
  - Disposal
  - Recovery/ Out-of-stocks

C. Food Factors
(3) Food Fraud
Discussion/ Enter Data

- This is a key factor when focusing on identifying root causes and prevention measures.
  - Understand the opportunity of the fraud, considering both internal and external mechanisms
  - Understand the action of the fraudster to choose detection and deterrent measures
  - Incorporate response in the overall standard operating procedures
- ***Action: Enter Data***

C. Food Factors
(4) Food Defense

4:15pm

C. Food Factors
(4) Food Defense
Is

- FDA/DHS focus on only terrorist attacks. The concept could expand to any deliberate attack ranging from malicious tampering to disgruntled employee contamination to a terrorist attack.
  - **Act:** Intentional/Health Threat
  - **Modes Operandi:** Awareness of Harm, Panic
  - **Impact:** Recall, legal liability, contamination/ recovery, loss of brand equity, etc.

C. Food Factors
(4) Food Defense
Trend

- Food Defense has been an industry and agency focus since the formation of DHS after 9/11. While the counter-terrorism focus is still intense, a wider range of threats is considered.
  - Programs have been integrated into overall food quality/ quality assurance functions
  - Risk-Based Approach, but expanding to “sensational” risks
  - Engage in public/private partnerships

C. Food Factors
(4) Food Defense
Contaminant 1 - Biological

- For each of the contaminants, several details are considered:
  - Intent and Capabilities of the Attacker
  - Delivery Method
  - Contaminant Utilized

C. Food Factors
(4) Food Defense
Contaminant 2 – Physical/Handling

- For each of the contaminants, several details are considered:
  - Intent and Capabilities of the Attacker
  - Delivery Method
  - Contaminant Utilized

C. Food Factors
(4) Food Defense
Contaminant 3 – Chemical/Radiological

- For each of the contaminants, several details are considered:
  - Intent and Capabilities of the Attacker
  - Delivery Method
  - Contaminant Utilized

C. Food Factors
(4) Food Defense
Contaminant 4 - Other

- The fourth “contaminant” is included for emerging risks. It is important to maintain vigilant and diligent monitoring of new threats.
  - Where are there new threats - changes in perception or other corporate threats
  - What new types of threats are in other industries
  - What product or production changes create new opportunities (gaps or risk exposure)

C. Food Factors
(4) Food Defense
Risk

- Potentially catastrophic, even with business interruption insurance. More likely small attacks, but still very costly.
  - Recalls : Class I, II, & III
  - Disposal
  - Recovery/ Out-of-stocks

C. Food Factors
(4) Food Defense
Discussion/ Enter Data

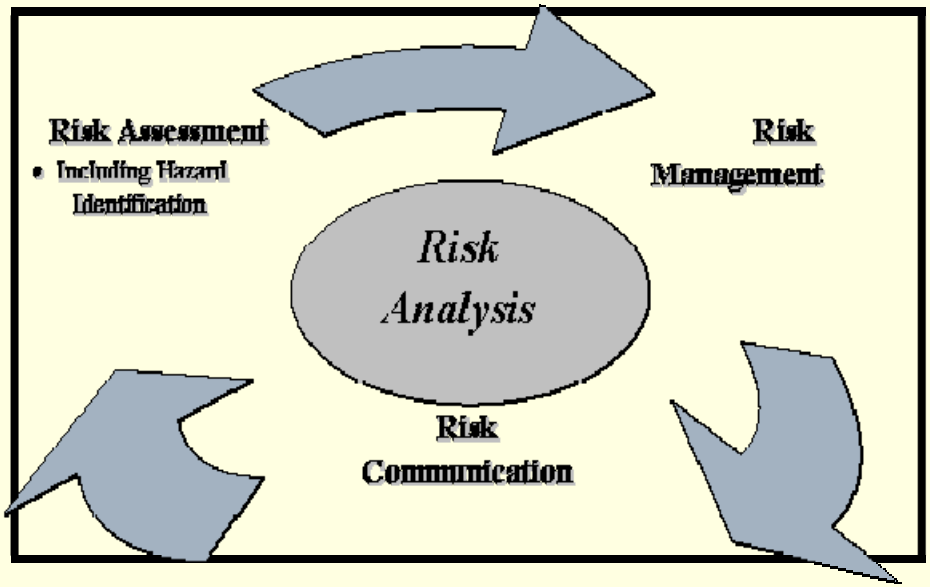
- This factor has a expanded focus from just counter-terrorism to other attacks. The entire spectrum of food risks are important to consider on a continuum… an integrated continuum.
  - Understand the opportunity of the threat – utilize tools such as Carver+Shock
  - Incorporate response in the overall standard operating procedures
  - Engage in public/private partnerships
- ***Action: Enter Data***

D. Risk

4:30pm

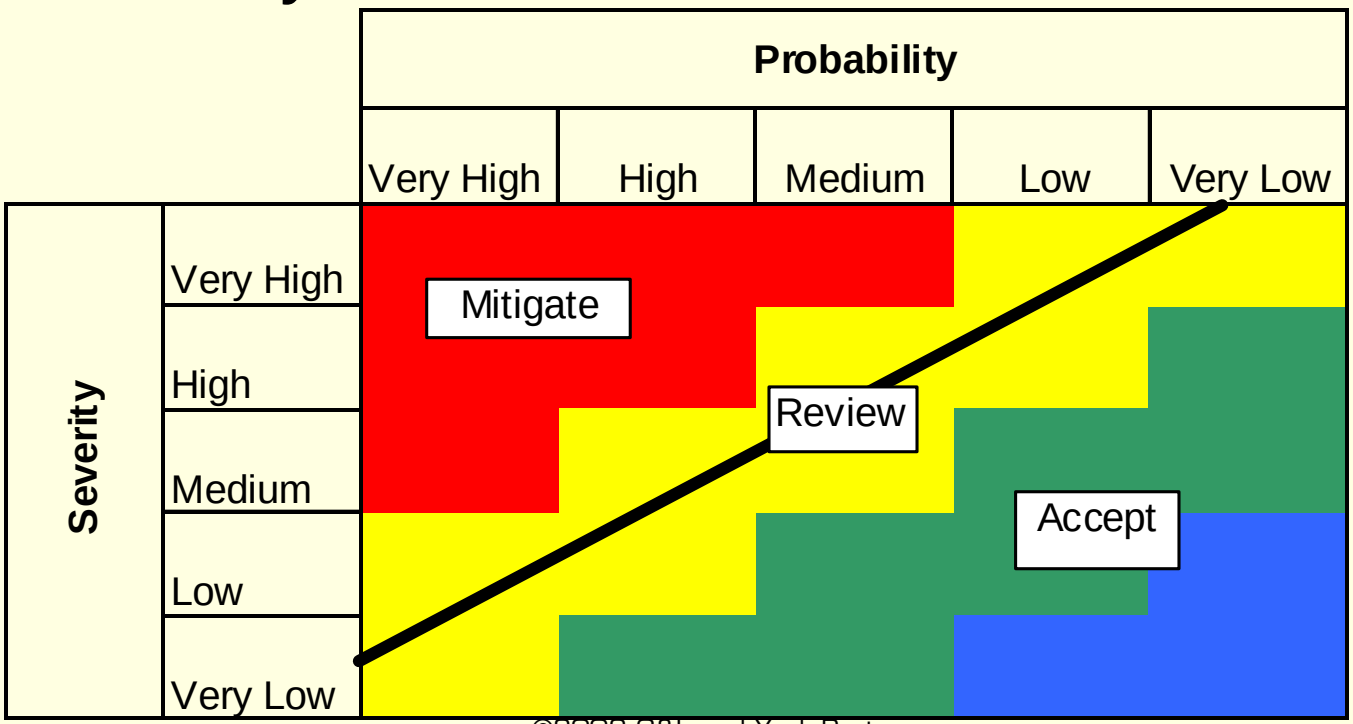
D. Risk
Is

- Risk Analysis is an overall process that includes:
  - **Risk Assessment** – including the sub-routine of hazard analysis
  - **Risk Management** – risk mitigation, risk transfer, or risk acceptance. E.g. HACCP, FMEA, FMECA, GMP, GAP, PHA, etc.
  - **Risk Communication** – including an ongoing review



D. Risk
Is (2)

- Enterprise-wide risk management includes an overall risk matrix, or risk summing: Where is food safety? Above or below the line?



D. Risk
Trends

- Enterprise Risk Management (ERM) and a Chief Risk Officer (CRO) are becoming more common.
  - Understand and speak the language of risk
  - Use a Risk Matrix and Risk Summing
  - CFO/CRO expanding focus to all-hazards within ***their structure***

D. Risk
Models and Tools

- HACCP, GMP, GAP, etc.
- Operational Risk Assessment (Matrix)
- Carver+Shock
- FDA “ALERT” Initiative
- Specific Models and Tools
- Organizations and Actions
  - Food Safety Alliance for Packaging (FSAP): Packaging HAACP
  - Society for Risk Analysis (SRA): Emerging Risk Assessment
  - DHS Import Food Vulnerability Assessment (6/2009)
  - FDA Economic Motivated Adulteration (5/2009) CARVER + Shock

D. Risk
Risk Management and Mitigation

- After identifying the risks, examine how they are managed in addition to other mitigation options
  - Act on the assessed risks, record
  - Mitigation options: what actions address what specific risks (detail of matrix), what is the cost and probability of success.
  - Review on a regular basis in relation to the Risk Matrix… above or below the line

D. Risk

Risk Communication and Recovery

- Communicate the risks and the risk management processes, and also include all these risks in crisis management programs
  - Communicate risks to underscore the importance of the operating procedures
  - For Fraud and Defense, communicate with extreme care. Work closely with legal and corporate security ***to not inadvertently expose your company to a bigger risk***.
  - Include all these food risks in crisis management programs, and conduct mock events.

D. Risk
Regulations

- HACCP, GMP, GAP
- Sarbanes-Oxley
- ISO Standards
- FDA Bioterrorism Act (Traceability)
- FDA FD&C Act – 505D Pharmaceutical Security
- QALY: Quality Adjusted Life Years
- GFSI, BRC, and Third Party Standards

D. Risk

Risk Assessment vs. Quality Control

- Consider the assessment of a finite & known threat versus an infinite & unknowable threat.
  - Many “Risk” programs are essentially “Quality Control” – managing the known threats
  - Enterprise Risk Management
  - Constantly assess what risks should be in the risk assessment – ***the HA in HACCP***

D. Risk
Discussion/ Enter Data

- The concept of risk is expanding from managing the known to managing all possible risks to a product, process, or business.
  - Identify Risks
  - Quantify in CFO/CRO terms – identify the managers and ***their process***
  - Provide risk analysis, as well as mitigation and recovery details
- ***Action: Enter Data***

E. Wrap-Up and Next Steps

4:45-5:00PM

Adjourn

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I. Food Quality

				Total Risk Severity ($)		Total Risk Probability ($/1 yr)		Weighted Risk ($)
			Total Risk	$ -	x	0%	=	$ -
	Examples	Event Reaction	Type of Cost			*1,25,50,75,99%*		
A - Biological					x		=	$ -
B - Physical					x		=	$ -
C - Chemical					x		=	$ -
D - Other					x		=	$ -

II. Food Safety

				Total Risk Severity ($)		Total Risk Probability ($/1yr)		Weighted Risk ($)
			Total Risk	$ -	x	0%	=	$ -
	Examples	Event Reaction	Type of Cost			*1,25,50,75,99%*		
A - Biological					x		=	$ -
B - Physical					x		=	$ -
C - Chemical					x		=	$ -
D - NA for HACCP					x		=	$ -

III. Food Fraud

				Cost Per Event ($, or over 10 yrs)		Total Risk Probability ($/10yr)		Weighted Risk ($)
			Total Risk	$ -	x	0%	=	$ -
	Examples	Event Reaction	Type of Cost			*1,25,50,75,99%*		
A - Direct Health Threat					x		=	$ -
B - Indirect Health Threat					x		=	$ -
C - Economic Threat Only					x		=	$ -
D - Other					x		=	$ -

IV. Food Defense

				Cost Per Event ($, or over 10 yrs)		Total Risk Probability ($/10yr)		Weighted Risk ($)
			Total Risk	$ -	x	0%	=	$ -
	Examples	Event Reaction	Type of Cost			*1,25,50,75,99%*		
A - Biological					x		=	$ -
B - Physical					x		=	$ -
C - Chemical					x		=	$ -
D - Insurance Premium					x		=	$ -