

# **The Bioterrorism Act and Food Security**

Department of Grain Science and Industry

Kansas State University

Fourth Heat Treatment Workshop

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# We'll Discuss...

- The Bioterrorism Act
- Threats to Food Security
- Risk Management Tools
- Incident/Crisis Response Plan
- Informal Survey of the Industry
- Resources

# The Bioterrorism Act

- The events of 9/11/02, reinforced the need to enhance the security of the United States food supply. Congress responded by passing the ***Public Health Security and Bioterrorism Preparedness and Response Act of 2002***. President Bush signed it into law June 12, 2002.

# The Bioterrorism Act

- Title III, Subtitle A: Protection of the Food Supply
- Four provisions require regulations
  - Section 303, ***Administrative Detention***
  - Section 305, ***Registration of Food Facilities***
  - Section 306, ***Establishment and Maintenance of Records***
  - Section 307, ***Prior Notice of Imported Food Shipments***

# The Bioterrorism Act

- Section 303, *Administrative Detention*
  - Authorizes detention of food presenting a threat of serious adverse health consequences or death to humans or animals
  - No time frame specified

# The Bioterrorism Act

- Section 305, *Registration of Food Facilities*
  - Requires registration of facility with FDA
    - Facility is any factory, warehouse, or establishment, including importers
    - Exempts farms, restaurants, retail food establishments, nonprofit food establishments (food prepared/served directly to consumer), and fishing vessels
  - December 12, 2003 facility & reg. deadline

# The Bioterrorism Act

- Section 306, *Establishment and Maintenance of Records*
  - Requires establishment of requirements for the creation and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food
    - Exempts farms and restaurants
  - December 12, 2003 regulation deadline

# The Bioterrorism Act

- Section 307, *Prior Notice of Imported Food Shipments*
  - Requires that prior notice of food shipments be given to FDA
    - Prior notice: no less than 8 hours and no more than 5 days
  - December 12, 2003 regulation deadline



# Threats to Food Security

- Biological warfare against livestock and crops
  - Iraq admittedly researched wheat smut rust as a biological agent
- Contamination of imported foodstuffs
  - FDA spot-checks less than one percent of imported foods

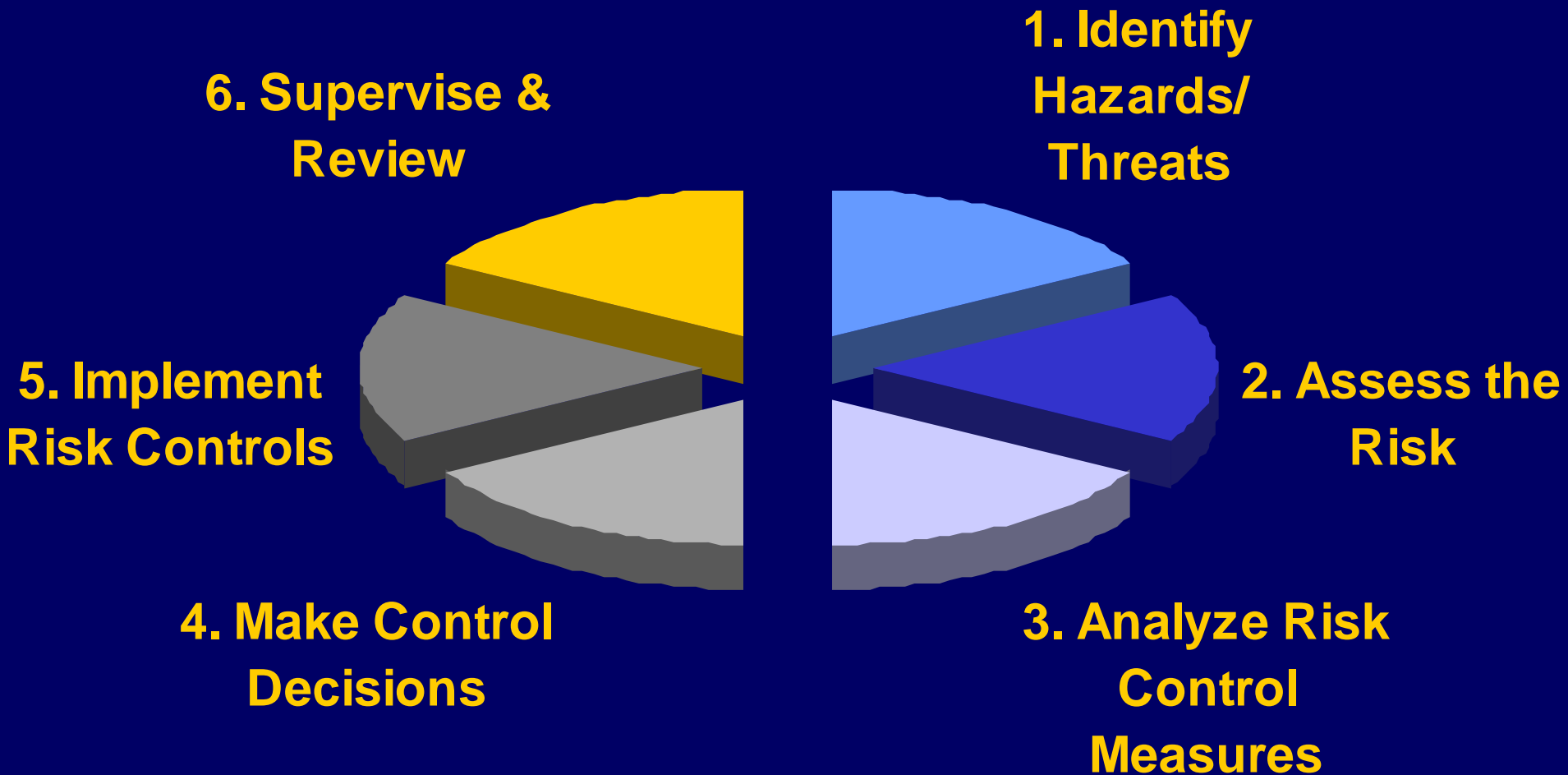
# Threats to Food Security

- Contamination of water supply
  - Be alert to changes in potability profile
- Tampering of food
  - Certain bacteria and viruses could be deliberately added

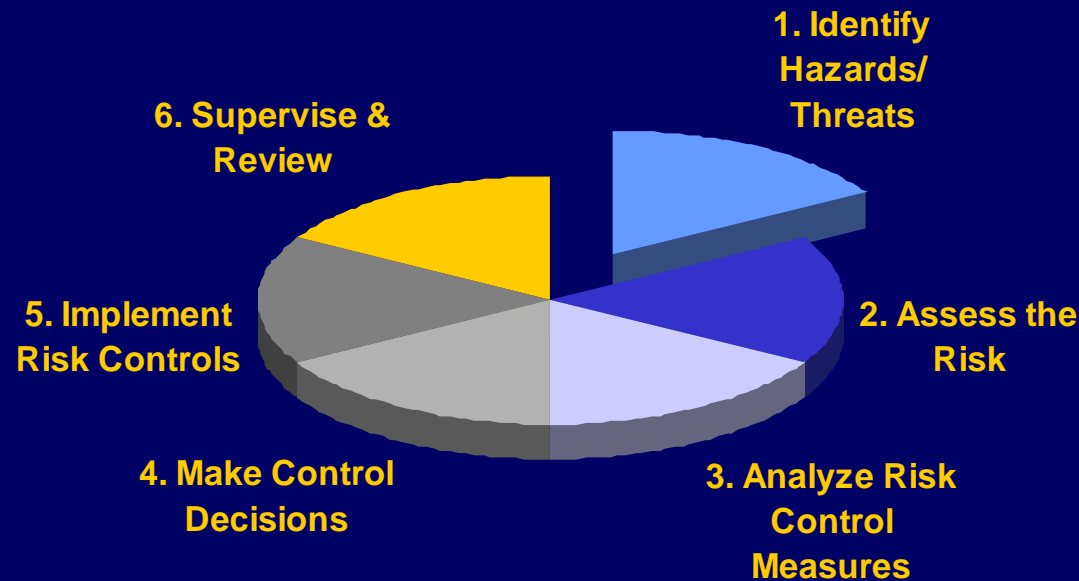
# Risk Management Tools

- ORM (Operational Risk Management)
- TEAM (Threat Exposure Assessment & Management)
- HACCP (Hazard Analysis Critical Control Points)

# ORM / TEAM



# Step 1.



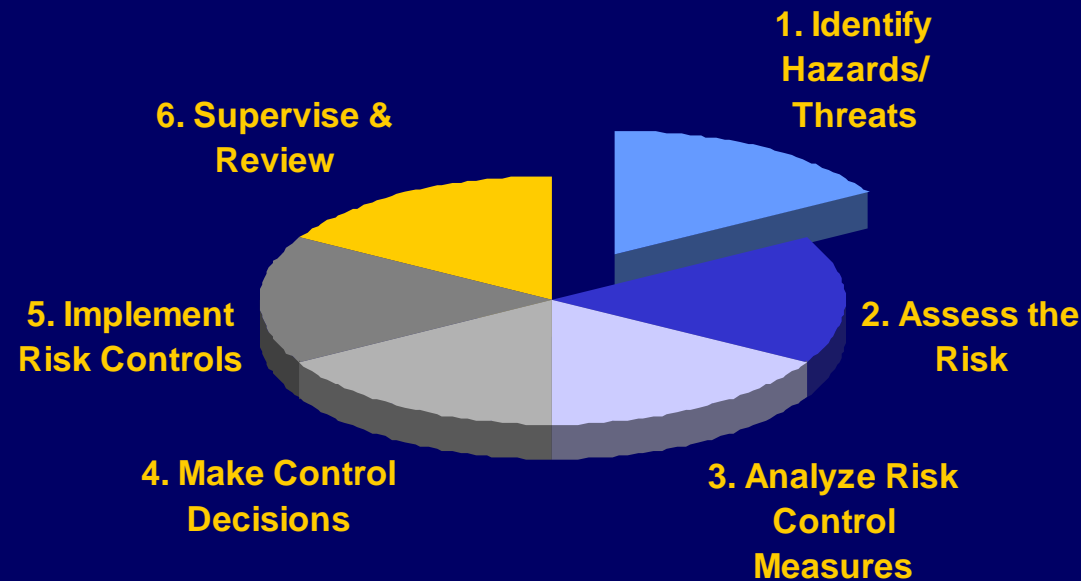
- Hazard/Threat

- Any real or potential food security condition that can cause illness, injury or death, property damage or business degradation

- Systemic Causes (5M)

- Man root
- Machine
- Means
- Management
- Mission

# Step 1.

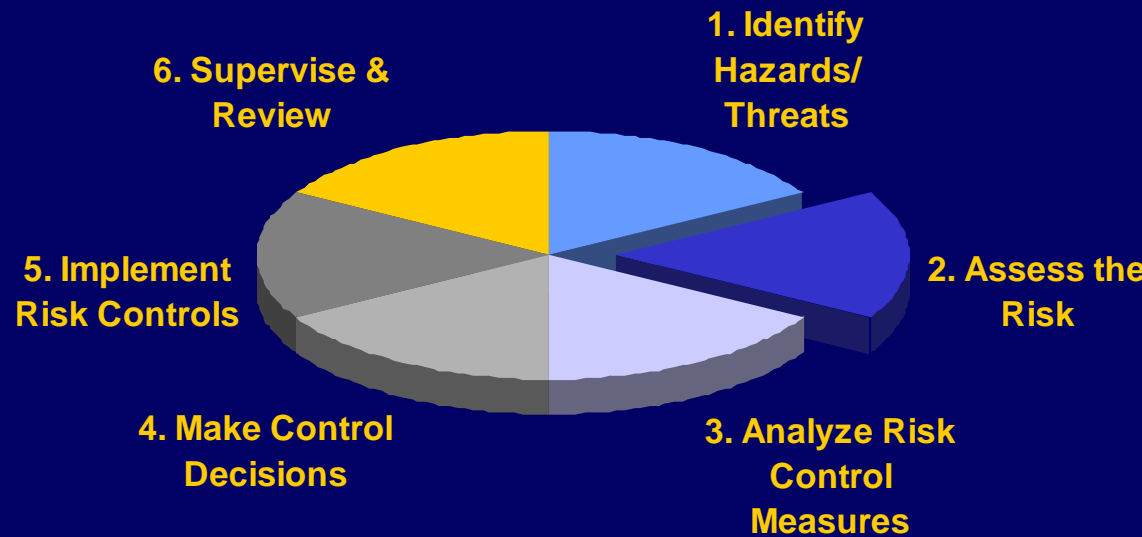


- ID Tools

- Operations analysis
- Scenario process
- Site reviews

- What if
- Logic diagrams
- Cause and effect

# Step 2.



- Risk

- The probability and severity of loss from exposure to the hazard/threat

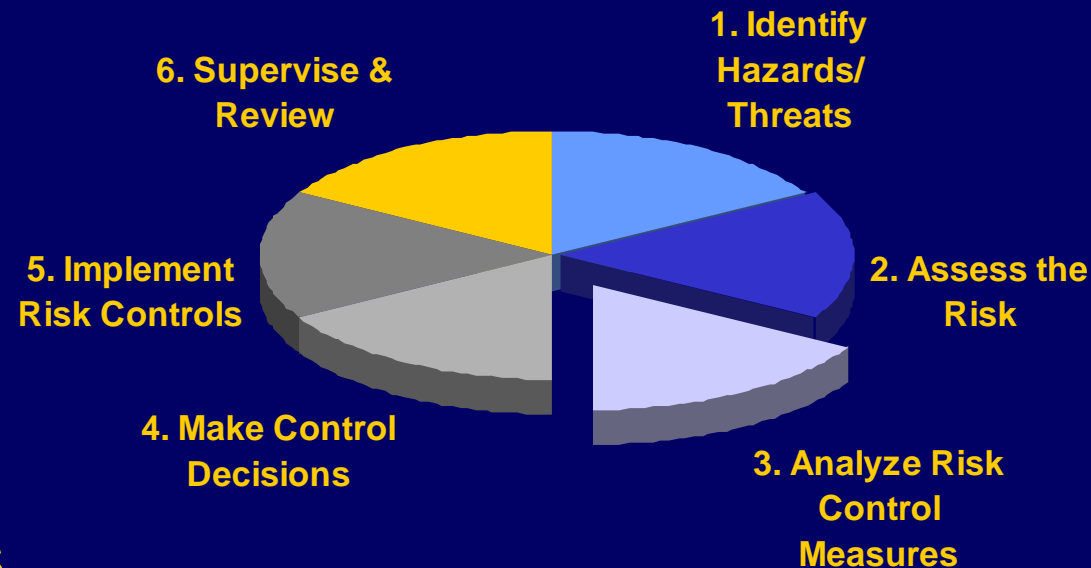
- Exposure expressed in terms of time, proximity, volume, or frequency

# Step 2.

			Probability					
			Frequent	Likely	Occasional	Seldom	Unlikely	
			A	B	C	D	E	
S E V E R I T Y	Catastrophic	I	Extremely					
	Critical	II	High	High				
	Moderate	III		Medium				
	Negligible	IV					Low	
			Risk Levels					



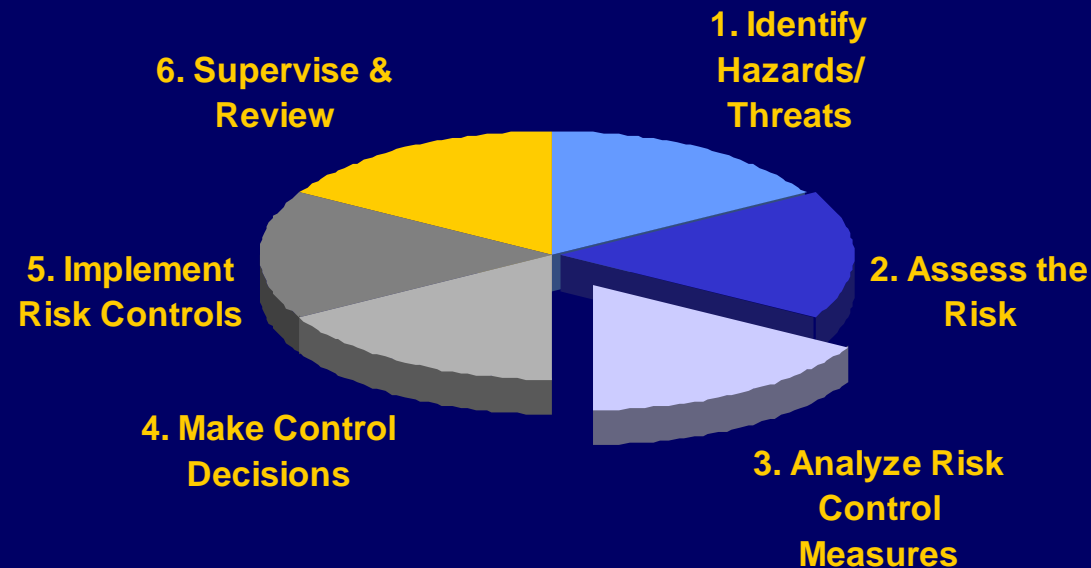
# Step 3.



- Control measures reduce or eliminate the exposure, probability, or severity of risk

- Action steps
  - Identify control options
  - Determine control effects
  - Prioritize control measures

# Step 3.



- **Principal Control Options**

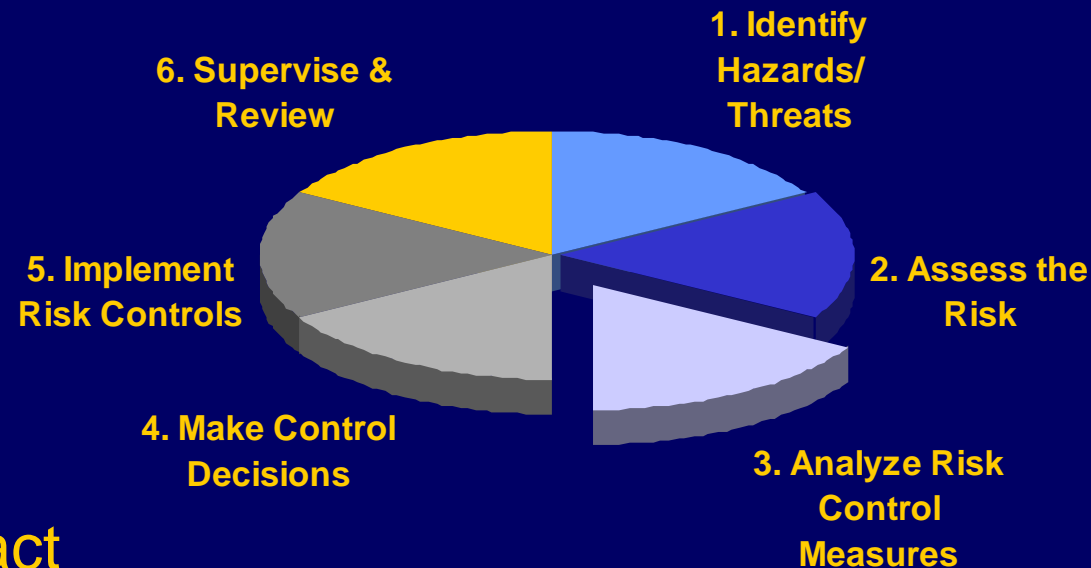
- Reject
- Avoid
- Delay
- Transfer
- Spread
- Compensate
- Reduce

- **Supporting control activities**

- Train & educate
- Engineer
- Improve task design
- Guard
- Warn
- Motivate
- Limit exposure
- Selection of personnel
- Reduce effects
- Rehabilitate

# Step 3.

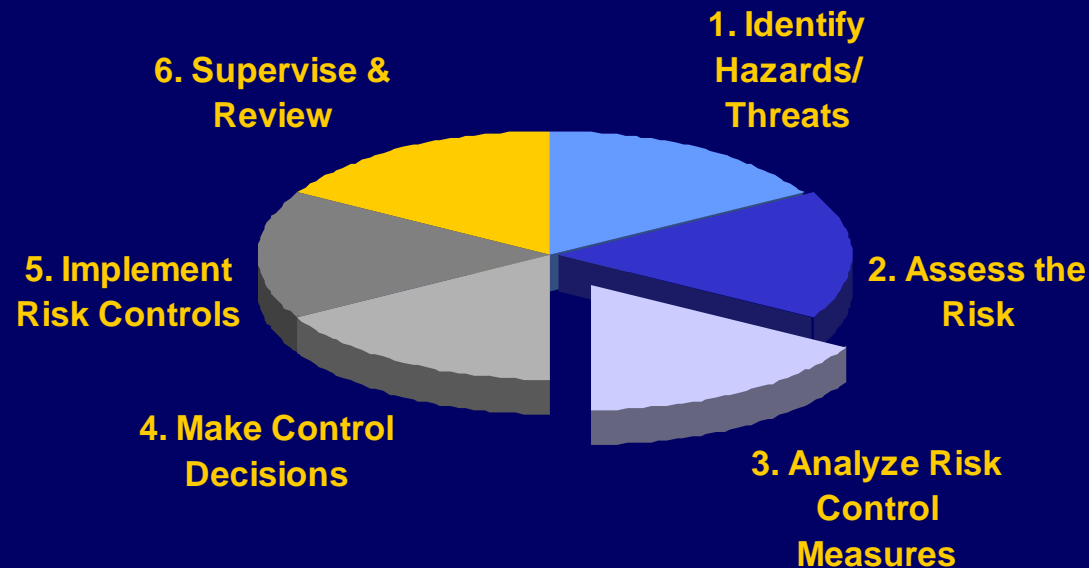
- Control effects
  - Estimate the impact on exposure, probability, and severity
  - Consider control costs



- Understand the interaction of control options

# Step 3.

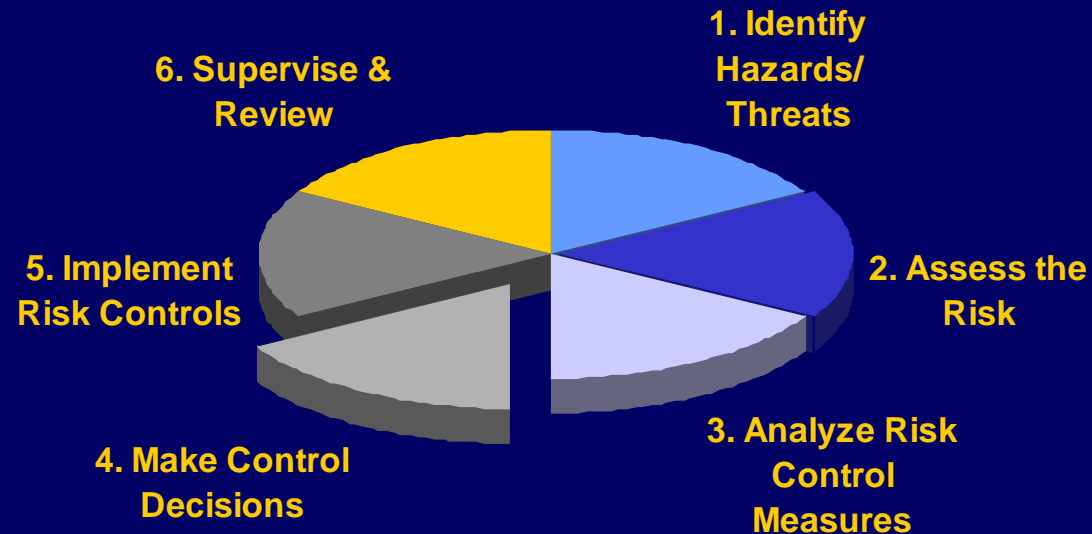
- Prioritize control measures
  - Focus risk control measures where they have maximum impact



- Involve operators
- Benchmark existing risk control options

# Step 4.

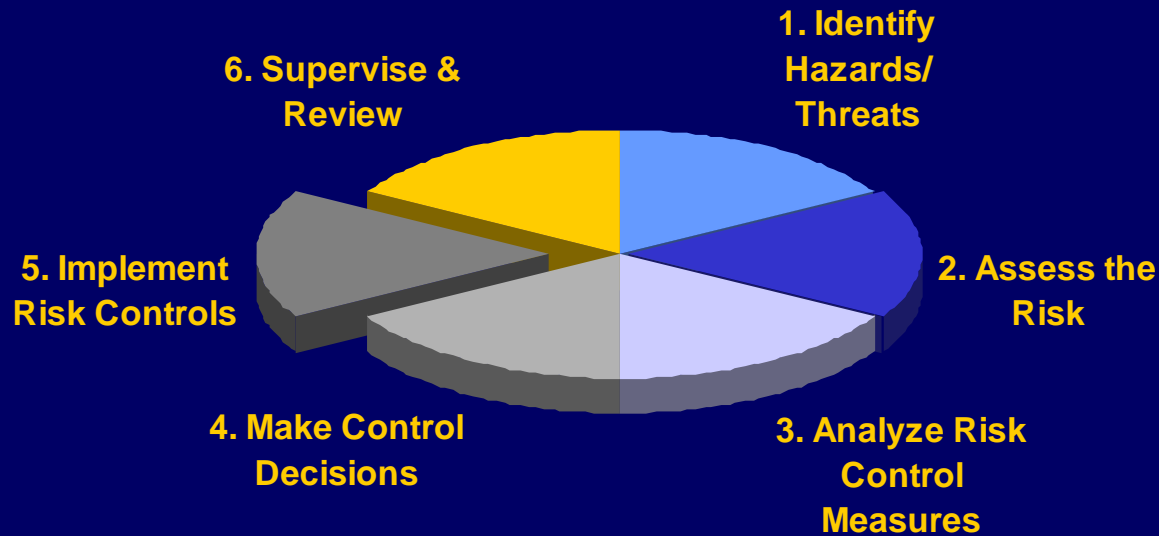
- Make control decisions
  - Right time
  - Right level



- Mission supportive

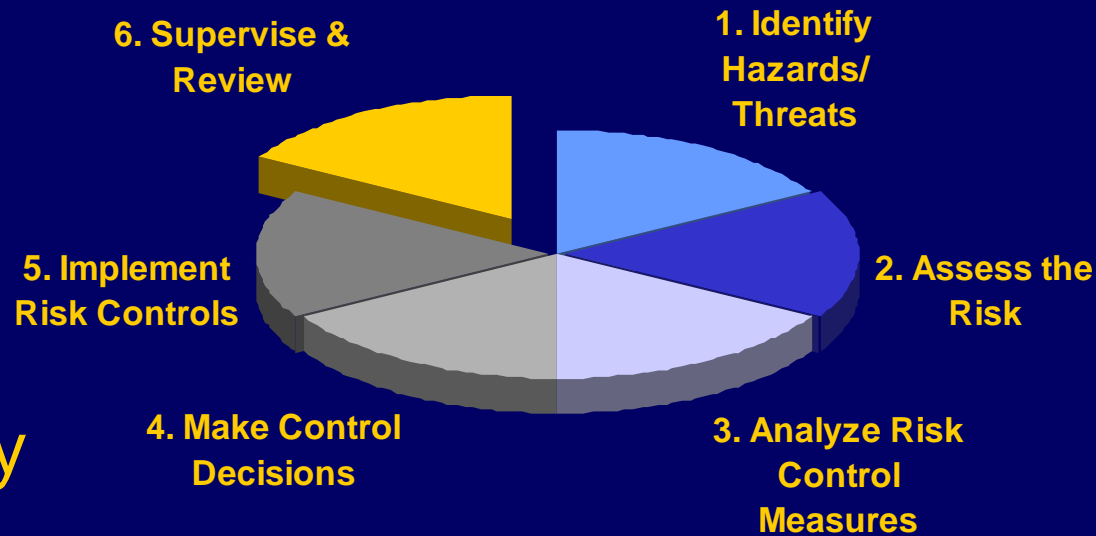
# Step 5.

- Make implementation clear
  - Be specific
  - Determine metrics
  - Integrate
  - Frame within culture
  - Document



- Establish accountability
- Provide resources
  - Standards
  - Tools
  - Training
  - Feedback

# Step 6.



- Supervise like any other leadership action
- Review by conducting a risk assessment after controls are in place to ensure risks are reduced
- Apply the process as a cycle
  - Tie back to step one

# HACCP

- Conduct a hazard analysis
- Identify critical control points (CCP)
- Establish critical limits for each CCP
- Establish monitoring procedures
- Establish corrective actions
- Establish record-keeping procedures
- Establish verification procedures



# Food Security HACCP

- Ingredients and products entering plant
- Individuals and vehicles entering plant
- Facility (external and internal) and processes
- Products leaving the facility

# Incident/Crisis Response Plan

- Reporting procedures
- Emergency evacuation plans
- A plant plan at the local fire department or in a secure location outside the plant
- Strategy for continued production
- Effective recall policy
- Relationship with qualified forensic lab
- Prepared press and customer statements
- Designated spokesperson

# Informal Survey of the Industry

- The “Act” has impacted food security practices across the industry
  - “tightened-up things that needed to be done for years”
  - “lots more documentation”
  - “more focus on seals and transportation security”
  - “created structured food security programs and training”
- The majority is working on paperwork, but has not yet registered facilities

# Informal Survey of the Industry

- Larger companies implemented more of the FDA voluntary guidelines than smaller ones
  - Key-pads at facility entrances
  - Lighting
  - Employee screening
  - Water supply programs
  - Non-employee identification
- Threat assessment tools
  - “HACCP and common sense”
  - Numerical scoring system using probability and severity of incident values
  - Cross-functional teams

# Informal Survey of the Industry

- Challenges exist
  - Capital outlay
  - Railcar and truck integrity
  - Controlling water supply
  - “Prior Notice” regulation is a logistical nightmare, especially with LTLs
  - Securing and/or defining perimeter
  - Maintaining safe exits (in case of fire) while securing entrances
  - Training
  - Employee commitment

# Resources

- FDA food security guidance documents
  - [www.cfsan.fda.gov/~dms/secguid.html](http://www.cfsan.fda.gov/~dms/secguid.html)
- The Bioterrorism Act
  - [www.fda.gov/oc/bioterrorism/bioact.html](http://www.fda.gov/oc/bioterrorism/bioact.html)
- GAO report on food processing security
  - [www.gao.gov/new.items/d03342.pdf](http://www.gao.gov/new.items/d03342.pdf)
- July 23, 2003, FDA progress report
  - [www.fda.gov/oc/initiatives/foodsecurity/](http://www.fda.gov/oc/initiatives/foodsecurity/)
- Industry Associations
- Universities

# Help Keep Our Nation's Food Supply Secure!

- Prior planning is crucial
- Keep the risk in perspective
- Collectively, our successful efforts to thwart bioterrorism will ensure consumer confidence in food products