

US EPA ARCHIVE DOCUMENT



Microbiological Risk Assessment Activities within the FDA/CFSAN

Sherri B. Dennis, Ph.D.
Food and Drug Administration
Center for Food Safety and Applied Nutrition

Center for Food Safety and Applied Nutrition (CFSAN)



Mission:
Promote and protect public health by ensuring that our food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled

History



1906 – Dining room of “poison squad”: A direct approach to risk assessment

- FDA/CFSAN has a long history of conducting safety assessments and risk assessments for food additives and chemicals
- Since 1999 FDA/CFSAN has been conducting complex quantitative risk assessments for microbial pathogens

An Integral Part of Daily CFSAN Activities with Multiple Offices Involved

- OFAS: Safety assessments as part of pre-market food additive petition review
- OFS, Chemical Hazards Assessment Team: Safety/risk assessments of industrial chemicals and naturally occurring contaminants
- OFDCER, Risk Assessment Coordination Team: Major risk assessments with center-wide interest
- OFDCER, Food Defense Team: Vulnerability and threat assessments
- ORPSS, Division of Economics: Economic analysis that integrates with risk assessment to generate cost-benefit analysis
- ONLDS: Safety/risk assessments of new dietary supplements and infant formulae
- Also, standing internal advisory committees (CAC/QRAC); subject matter experts serving on *ad hoc* teams; math/stat support

A Wide Range of Risk Assessment/Risk Analysis Work Products:

- Safety Assessments
- Qualitative Risk Assessments
- Risk Profiles
- Quantitative Risk Assessments
- “Rapid Response” Assessments
- Food Defense Assessments/Evaluations
- Risk/Benefit Analysis

Examples of Quantitative Microbiological Risk Assessments

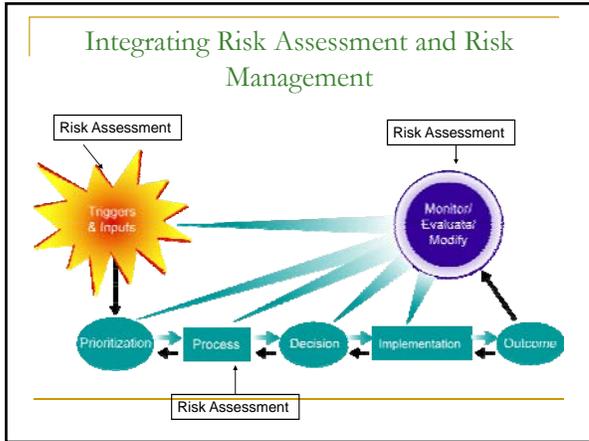
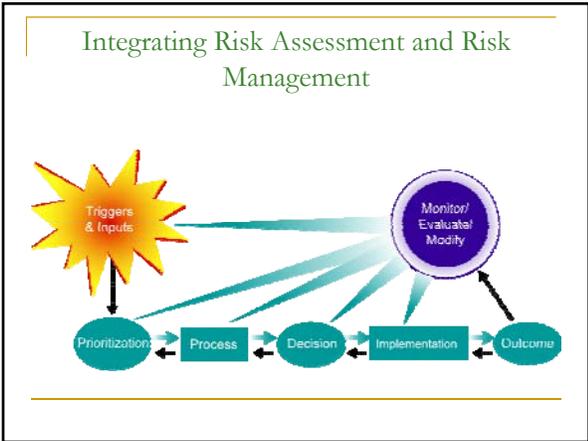
- Risk Ranking/ Comparative
 - FDA/FSIS *Listeria monocytogenes* in RTE foods
- Product/Pathogen Pathway
 - FDA *Vibrio parahaemolyticus* in oysters
- Geographical
 - Introduction of BSE (Harvard)
- Risk/Risk
 - Use of “active chlorine”

Recent Advancements ...

- Developed and implemented risk assessment and risk management frameworks
- Working with others to improve communication and coordination of risk assessments
- Applying new approaches and applications of risk assessment
- Supporting education/training for conducting risk assessment
- Building systems to manage and share data

Risk Assessment and Risk Management Framework Documents

The image shows two document covers. The left one is white with black text: 'The Center for Food Safety and Applied Nutrition, Food and Drug Administration', 'Initiation and Conduct of All Major Risk Assessments within a Risk Analysis Framework', 'A Report by the CFSAN Risk Analysis Working Group', 'March 2003'. The right one is yellow with a compass rose logo and text: 'Center for Food Safety and Applied Nutrition, Food and Drug Administration, Department of Health and Human Services', 'FDA', 'CFSAN's Risk Management Framework', 'December 2003'.



Working with Others & Building Capacity

Interagency Risk Assessment Consortium

"Better communication and coordination of risk assessment activities is essential for improved food safety decision-making"

 FSM, 2006

- Federal agencies with food safety missions
- Promote the conduct of scientific research to facilitate risk assessment
- Sponsor workshops
 - Data quality, peer review, data utility, risk ranking models, relating microbiological testing and criteria to public health goals

For more information see www.foodrisk.org

International Impact

- The United States has been on the forefront of the application of microbiological risk analysis to international standards setting
- FDA/CFSAN provides a high level of support to international organizations such as FAO/WHO, CODEX, JECFA, JEMRA
- Examples:
 - *Vibrio parahaemolyticus* in raw oysters
 - *Vibrio vulnificus* in seafood
 - *Vibrio cholera* in shrimp
 - *Enterobacter sakazakii* in infant formula
 - *Listeria monocytogenes* in ready-to-eat food



Educational Site Visits

- Why go on a site visit:
 - Better understand the food industry and see first-hand industry control measures; differences between practices at different facilities
 - Establish a relationship with industry stakeholders (they are a source of data and information)
- Where we went... (examples)
 - Smoked seafood manufacturing plant
 - Cheese manufacturing plant
 - Produce farms
 - Fresh-cut/ fresh processing facilities
 - Ships (commercial cruise and Naval vessel)

Using Internet Resources

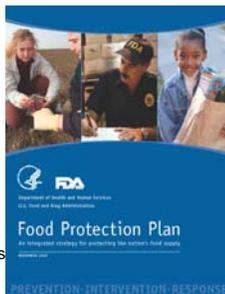
- www.foodrisk.org
A resource for risk analysis professionals
- www.ra4food.org
JIFSAN Risk Analysis Professional Development Program; Distance Learning



New Approaches & Applications

FDA's 2007 Food Protection Plan

- Integrate food safety & food defense
- Focus on the entire product life cycle
- Prevention, intervention, response
- Target resources to achieve maximum risk reduction
- Use science & modern technology system
- Seeking public comment
 - Electronic comments can be submitted to <http://www.regulations.gov>. All comments should be identified with docket number FDA-2008-N-00188.



Software for Vulnerability Assessment



- Identifies vulnerabilities within a facility using the CARVER + Shock Methodology
- Version 1 targets manufacturers and processors
- Version 2 will expand use for farms, retail, food service
- Available for download, free of charge

www.cfsan.fda.gov/fooddefense

The CARVER + SHOCK Process



- Create flow diagram; select production steps (nodes)
- Assess and score each node for the 7 factors (CARVER+S) using a value between 1 and 10
- Total node scores are compared and ranked

Using Microbial Risk Assessment for Decision Making

Uses for Microbiological Risk Assessment

- Know where to look
 - Set priorities/ allocate resources
 - Identify steps along "farm to fork" continuum that are "major contributors" to risk
- Evaluate effectiveness of interventions
 - Potential or equivalent control measures
 - Proposed standards and criteria
 - Contribution of compliance to risk management
- Inform communication/outreach messages
 - Determine subpopulations "at increased risk"
 - Assess uncertainty and variability

Example 1: The *Listeria* "Problem"

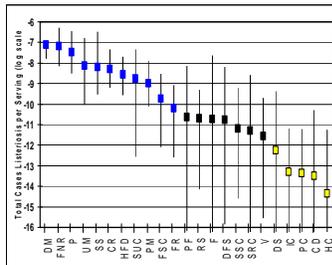
Which foods should receive the most regulatory attention in order to improve public health?



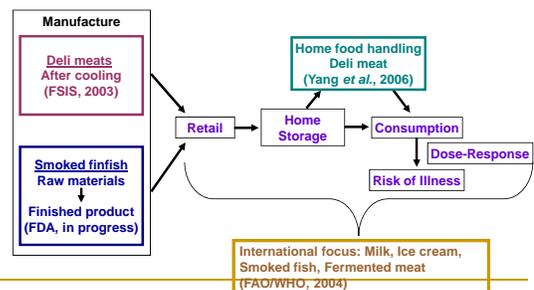
Risk Ranking Assessment

2003 *Listeria* RTE Foods Risk Assessment

- Priority setting:
 - Surveillance
 - Research
 - New risk assessments
- Action plan
- Communication messages
- Guidance; 2008 draft CPG



2003 LM Model: Building Block For New Risk Assessment Efforts



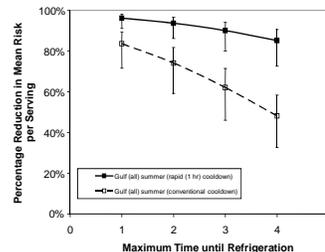
Example 2: The *Vibrio* "Problem"

- What factors contribute to the risk of becoming ill from consumption of raw oysters?
- What is the impact of different control measures on public health?
- Product/Pathogen Pathway Analysis



2005 *Vibrio* in Raw Oysters Risk Assessment

- Evaluate control measures
- Support ISSC
- Trigger for
 - New tools (GIS/real-time RA)
 - Validation research (retail study)



Examples of Current Projects

- **Qualitative Assessments (Risk Profiles)**
 - Hepatitis A Virus/ produce
 - Norovirus/ transmission routes
 - *Listeria*/ produce
 - Pathogens/ raw milk cheese
- **Quantitative Assessments**
 - *Listeria*/ smoked finfish
 - *Listeria*/ soft cheese (w/ Health Canada)
 - Highly pathogenic avian influenza virus/ poultry & eggs (w/ USDA-FSIS, APHIS)
 - Pathogens in produce (contract)
 - Risk ranking model (contract)

The Future..

New Techniques/ Applications

- Cross-contamination models
- Integrate GIS/ spatial technology with risk assessment modeling
- Risk-based approaches to prioritization & work planning (strategic allocation of resources based on public health risk)
- Applications to nutrition, nanotechnology, AND MORE

Conclusion

To advance the field of microbiological risk assessment we must continue to:



- Learn from our experiences
- Develop new ways to address complex food safety issues
- Foster involvement of multi-disciplinary expertise

Acknowledgements...

Special thanks to:

Risk Assessment Coordination Team Staff:

- Wendy Fanaselle
- Marianne Miliotis
- Lori Papadakis

Visiting Scientists

- Villie Flari
- GunYoung Lee
- David Oryang

Food Defense Oversight Team Staff:

- Don Kautter
- Amy Barringer

Advisors:

- Robert Buchanan
- Faye Feldstein
- Susan Bernard