Microbiological Risk Assessment Activities within the FDA/CFSAN

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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

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.

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

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 formulas.
- 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

Integrating Risk Assessment and Risk Management

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

Interagency Risk Assessment Consortium

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

- 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](http://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
  - Enterbacter 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.

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

- 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

- Manufacture
- Deli meats
- After cooling (FSIS, 2003)
- Home food handling
- Deli meat (Yang et al., 2006)
- Retail
- Home storage
- Consumption
- Risk of illness
- International focus: Milk, Ice cream, Smoked fish, Fermented meat

- Smoke fish
- Raw materials
- Finished product (FDA, in progress)
- Dose-Response
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

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