Think About…

One thing you do that is RISKY…
Think About…

One thing you do that has NO RISK…
Risk

- Risk is everywhere
- Some risks more serious than others
- Zero risk is not an option
- Is unavoidable
- Is uncertain

By: Charlie Yoe
Risk Definition

• Risk = probability of an adverse event and the magnitude of the consequences

• Elements of risk:
  • Probability (or likelihood, chance)
  • Consequences (or impact)
  • Uncertainty
  • Ability to manage
Examples

- In animal health:
  Risk = chance of a disease being introduced in a country

- In food safety:
  Risk = chance of getting sick from foodborne pathogens
  \[= [\text{Hazard}] \times [\text{Exposure}]\]
Food Safety Hazard Concerns

- Misuse of food additives, colors and flavors
- Veterinary drug residues and use of growth promoters
- Animal feed additives
- Fertilizer and growing aids
- Irradiation
- Microbiological contamination
  - Ubiquitous
  - Re-emerging
  - Newly emerging
- Mycotoxins and other naturally occurring food toxicants
- Pesticide residues
- Pollutants
- Defective packaging and labeling
- Adulteration and tampering
- Extraneous matter
- Biopesticides & transgenic insects
- Inspection and sampling

By: Charlie Yoe
Traditional Food Safety System Focus

• Hygiene
• Inspection
• End product testing
• May include food laws & regulations, food control management, inspection & laboratory services, mechanisms for information, education & communication

By: Charlie Yoe
Changes in Food Production and Consumption

- Large scale production
- Global supply chains
- Relentless pressure to lower costs
- Temptation for economic adulteration
- Untrained food workers
- More food consumed outside the home

- More year round foods
- More exotic foods and imports
- Less time for food preparation-microwaves
- More immuno-compromised consumers
- Increasing importance of international trade

By: Charlie Yoe
Science-Based Food Safety System

- We need to...
  - Describe the risk (Risk Assessment)
  - Do something about (Risk Management)
  - Talk about it (Risk Communication)

Risk Analysis

By: Charlie Yoe
Risk Analysis

- A systematic way of gathering, evaluating, and recording information leading to recommendations for a position or action in response to an identified hazard
  - applied consistently
  - open, transparent and well documented
  - evaluated and reviewed as appropriate in the light of newly generated scientific data

By: Charlie Yoe
Risk Analysis

- These principles apply equally to issues of national food control and food trade situations and should be applied consistently and in a non-discriminatory manner.
- To the extent possible, the application of risk analysis should be established as an integral part of a national food safety system.
Why Do Risk Analysis?

- To improve the quality of our thinking before a decision is made — uncertainty is ubiquitous
- To help assure a safe domestic food supply
- To protect human, animal, and plant life and health
- Allow industry to innovate
- It’s essential for international trade

By: Charlie Yoe
International Trade – WTO

- World Trade Organization (WTO)
  - Established in 1995 to facilitate international trade by serving as a
    - forum for negotiating trade agreements
    - place to settle trade disputes
    - system of trade rules
  - Relevance for Food Safety
    - Sanitary and Phytosanitary (SPS) Agreement
Risk Analysis and WTO/SPS

- WTO members shall: *(in the context of food safety)*
  - Ensure that any measure applied only to the extent necessary to protect human life and health
  - Base their measures on risk assessment, taking into account the techniques developed by international organizations
  - Implement a measure that differs from international norms where a higher appropriate level of protection is a legitimate goal
  - Apply the principles of equivalency where a different measure in an exporting country achieves their appropriate level of protection
- Risk assessment as the system to develop and apply standards for foods in international trade
Risk Analysis framework

Risk Assessment
Scientific inputs

Risk Management
Decisions involving policy and values

Risk Communication
Interactive exchange of information and Options concerning risk

Codex Committee on Food Hygiene
“The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.”
Generic Risk Management Framework

**Preliminary risk management activities**
- identify food safety issue
- develop risk profile
- establish goals of risk management
- decide on need for risk assessment
- establish risk assessment policy
- commission risk assessment (if needed)
- consider results of risk assessment
- rank risks (if needed)

**Implementation of risk management decision**
- validate control(s) where necessary
- implement selected control(s)
- verify implementation

**Monitoring and review**
- monitor outcomes of control(s)
- several information sources for monitoring
- review control(s) where indicated

---

Codex Committee on Food Hygiene
Risk Analysis framework

Risk Assessment
Scientific inputs

Risk Management
Decisions involving policy and values

Risk Communication
Interactive exchange of information and Options concerning risk

Codex Committee on Food Hygiene
Risk Assessment - Codex Definition

“A scientifically based process consisting of the following steps:”

• (i) hazard identification
• (ii) hazard characterization
• (iii) exposure assessment
• (iv) risk characterization
“The identification of biological, chemical and physical agents, capable of causing adverse health effects and which may be present in a particular food or group of foods”

- Risk profile may be sufficient
- Identify specific risk factors
Risk Assessment – Hazard Characterization (ii)

“The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable”

- Dose-response relationship: levels of exposure to the hazard and the likelihood of different adverse health effects
  - morbidity/hospitalization/mortality/sequelae associated with different doses
- Data: animal toxicity studies, clinical human exposure studies and epidemiological data from investigations of illness
Risk Assessment – Exposure assessment (iii)

“The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures to other sources if relevant”

- Amount of hazard consumed by various members of the population
- [Concentration of the hazard / changes in concentration (increase/decrease)] X [food consumption pattern]
Risk Assessment – Risk Characterization (iv)

“The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment”

- Combines hazard characterization and exposure assessment to generate risk
- Describes uncertainty and variability
- May include comparative rankings
Risk Assessment

- Organizes the relevant science
- Answers risk manager’s questions
- Characterizes the risk
- Models of reality
  - Qualitative (descriptive model)
  - Quantitative (mathematical model)
    - Deterministic
    - Stochastic/Probabilistic
- A risk assessment model must fit a purpose
Qualitative Risk Assessment

- The process of compiling, combining and presenting evidence to support a statement about risk
  - Descriptive or categorical treatment of information
  - Is formal, organized, reproducible method based on science and sound evidence
  - Easy to explain to others
  - For routine non controversial tasks
  - When theory, data, time or expertise are limited
  - Good for establishing relative risks or evaluate relative impacts on risk mitigation strategies
  - Supports risk management decision making – but limited in the sense that does not provide a probability
Qualitative Risk Assessment - Example

“What is the probability of introduction and transmission of H5N1 HPAIV into the 1-km buffer zone surrounding a compartmentalised (integrated) poultry farm in Thailand?”

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Wild birds</td>
<td>Very low</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
<td>Very low</td>
<td>Medium</td>
</tr>
<tr>
<td>Live poultry</td>
<td>Very low</td>
<td>High</td>
<td>Very high</td>
<td>High</td>
<td>Very low</td>
<td>High</td>
</tr>
<tr>
<td>Free-ranging ducks</td>
<td>Very low</td>
<td>Low</td>
<td>Very low</td>
<td>Very low</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Fertilizers</td>
<td>Very low</td>
<td>Medium</td>
<td>Very low</td>
<td>Very low</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Humans</td>
<td>Very low</td>
<td>Medium</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>

From: Qualitative Risk Assessment of the Risk of Introduction and Transmission of H5N1 HPAI Virus for 1-km Buffer Zones Surrounding Compartmentalised Poultry Farms in Thailand
http://www.research4development.info/PDF/Outputs/HPAI/WP7_090216.pdf
Quantitative Risk Assessment

- Mathematical modeling
  - Deterministic model
    - Assumes inputs are known and fixed values with no randomness
    - A given input will always produce the same output
    - Model can be built using expected value, worst case estimates etc.
    - Difficult to interpret point estimates – there is no probability associated with the outcome
  - Stochastic/Probabilistic model
Quantitative Risk Assessment

- Mathematical modeling
  - Deterministic model
  - Stochastic/Probabilistic model
    - Values can be entered as probability distributions - incorporate randomness
    - Monte Carlo simulation allows to simulate uncertainly and variability in the values
    - Outcome has a probability associated with it
    - Allows for Sensitivity analysis – which inputs in your model impact more significantly the output
Risk Assessment

• Uncertainty
  • Reflects the level of knowledge the assessor has regarding the components of the risk assessment
  • More study, research, elicitation reduce uncertainty

• Variability
  • Refers to the fact that natural phenomena have inherent dispersion
  • Irreducible
Risk Analysis framework

- Risk Assessment: Science inputs
- Risk Management: Decisions involving policy and values
- Risk Communication: Interactive exchange of information and Options concerning risk

Codex Committee on Food Hygiene
Risk Communication - Codex Definition

“The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.”
Risk Communication & Generic RMF

Identification and selection of risk management options
- identify possible options
- evaluate options
- select preferred option(s)

Implementation of risk management decision
- validate control(s) where necessary
- implement selected control(s)
- verify implementation

Monitoring and review
- monitor outcomes of control(s)
- review control(s) where indicated

Preliminary risk management activities
- identify food safety issue
- develop risk profile
- establish goals of risk management
- decide on need for risk assessment
- establish risk assessment policy
- commission risk assessment
- consider results of risk assessment
- rank risks

WHO/FAO, 2006
Risk Communication

- Contributes to transparency
- Promotes broader understanding and acceptance of risk management decisions
- WTO/SPS Agreement requires governments to:
  - Notify other countries of any new or changed sanitary requirements which affect trade
  - Set up “enquiry points” to respond to requests for more information or new or existing measures
Tools for Risk Analysis

- Capacity building – training online and conventional classroom format
- **FoodRisk.org**
  - Online resource for food safety risk analysis
  - Risk assessment models
  - Raw data
  - Tools (i.e.: iRisk, food handling model)
  - Relevant literature and documents
- Tutorials
Hot Issues in Risk Analysis

- Risk-base sampling and inspection
- Development of quantitative microbiological metrics for risk management
  - Food safety objectives (FSO):
  - Performance objectives (PO)
  - Performance criteria (PC)

(Gorris, 2004)
Hot Issues in Risk Analysis

• Risk Prioritization
  • Optimize the use of financial resources by using science-based approach to improve public health and international trade
  • Healthy adjusted life years (HALY):
    • DALY: disability adjusted life years \(\rightarrow\) Global burden of disease (WHO)
    • QALY: quality adjusted life years
  • Methods to incorporate other measures that impact risk prioritization (e.g.: financial impact on economical sector, consumer perception and acceptance of risk)
    • Multi-criteria decision analysis (MCDA)
    • More transparent and accountable framework
Conclusions - Risk Analysis

- It is a systematic way of thinking about risk and organizing to solve problems
  - It is an ongoing activity
- Purpose oriented to find right problem
- It is the interface between science and values
- Data intensive
- Requires analytical and administrative capacities
Thank you

Questions?

Juliana M. Ruzante, DVM, MVPM, PhD
Risk Analysis Program Manager
Joint Institute for Food Safety and Applied Nutrition
University of Maryland
College Park, MD, USA
jruzante@umd.edu
1. 301.405.1780
www.jifsan.umd.edu
www.foodrisk.org