Risk Assessment Toolbox

Risk Analysis Training

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Risk Profiles in Codex

- ## PURPOSE:
    - "The risk profile is an abbreviated discussion paper that lays out the key elements of a MRM concern in order to facilitate decision-making on the part of the risk manager in relation to the need and scope of newly proposed work"

- ## SCOPE AND RATIONALE:
    - "Identify the food safety issue (microbial hazard & commodity of concern) and provide information required by the risk manager to make an informed decision on the need to undertake work on the subject"

Codex Committee on Food Hygiene Risk Profile Elements

- 1. Hazard-food commodity combination(s) of concern
- 2. Description of the public health problem
- 3. Food production, processing, distribution and consumption
- 4. Available options for control
- 5. Additional factors (e.g., consumer perceptions, economics, fair trade issues)
- 6. Risk assessment needs and questions for the risk assessors
- 7. Available information and major knowledge gaps

Risk Profile

- Can be viewed as a qualitative risk assessment combined with a qualitative control options assessment

- Often an early step in risk analysis process – used to develop hazard analysis

Risk Assessments Tools
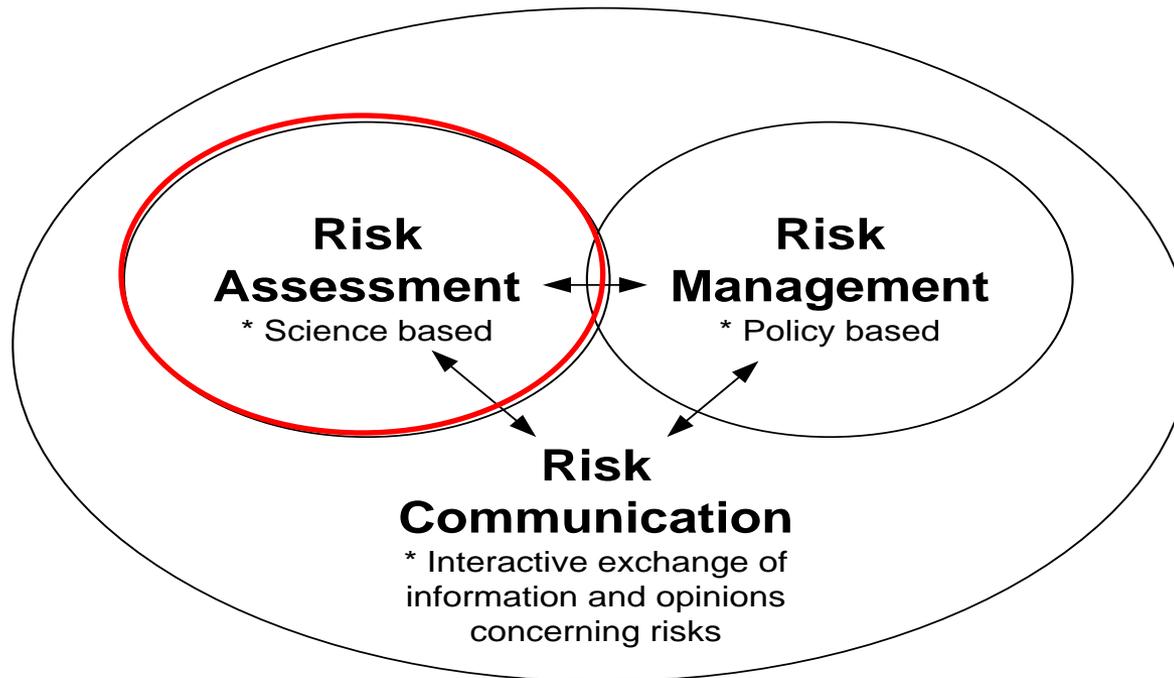
Food Safety Risk Assessments

- **There is a variety of different types of risk assessments**
- **Need the right tool for the right job**

- Chemical safety and risk assessment
  - Food/color additives
  - Pesticide residue risk assessment
  - Animal drug residues
  - Process safety
- Microbiological risk assessment

- Biological hazards risk assessments
  - Allergens
  - Nutrition
  - Naturally occurring toxins
- Food Defense
- Biotechnology
  - Genetically modified foods
- Pest risk assessment—plant and animal

Methodology

- ## Qualitative
  - Narrative, categorical (rating) or graded (ranking) non-numerical risk estimates

- ## Semi-quantitative
  - Narrative or categorical rankings converted into quantitative values for the purpose of further analysis
  - Validity of normal values can be questionable

- ## Quantitative
  - Numerical estimates of risk
    - Deterministic
    - Probabilistic/Stochastic

Qualitative RA

- Compiles, combines and presents evidence to support a non-numerical estimate and description of a risk.
    - Theory, data, time or expertise are limited
    - Routine non-controversial tasks
    - To assure consistency and transparency in handling risk
    - For big broadly defined problems where quantitative risk assessment is impractical
    - When risk management needs can be met qualitatively

- May be used in conjunction with a risk profile

Quantitative RA

- Numerical expressions of risk
  - Generally more informative than qualitative estimate
  - Preferred when data and resources are available
- Comes in two forms: Deterministic or probabilistic
- Generally considered more resource/data intensive than qualitative risk assessment

Assessing Food Safety Risks

- The product of a quantitative risk assessment is a mathematical statement based on cumulative probabilities of certain events happening or the chance of harm following exposure to a biological agent capable of causing harm
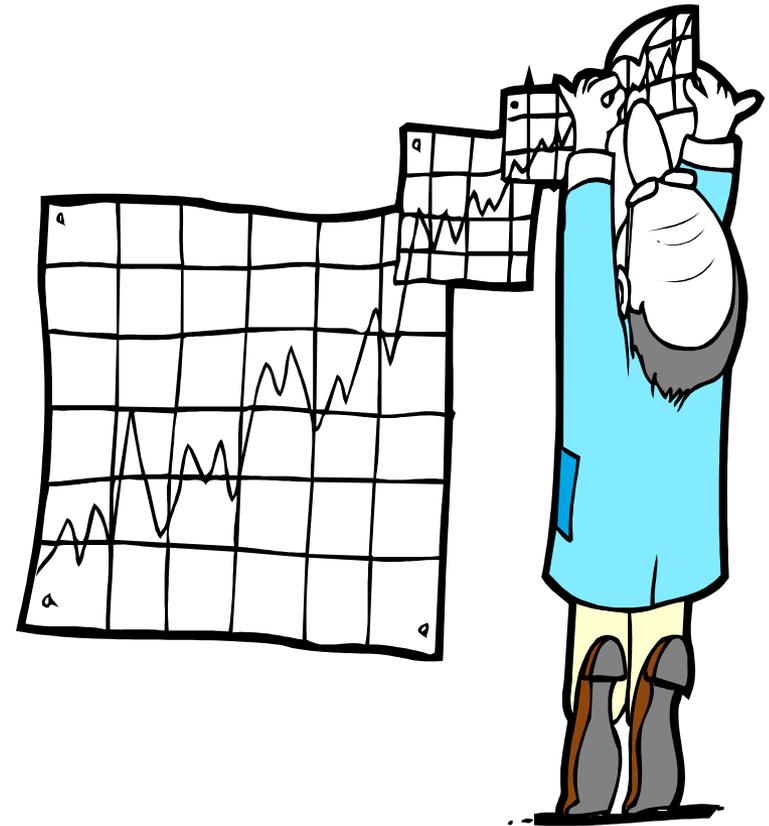
Consider Variability and Uncertainty

- In deterministic quantitative risk assessments we pick a single point in the distribution of key variables
  - Mean
  - 95% point
- Selection of assumed value can greatly influence results
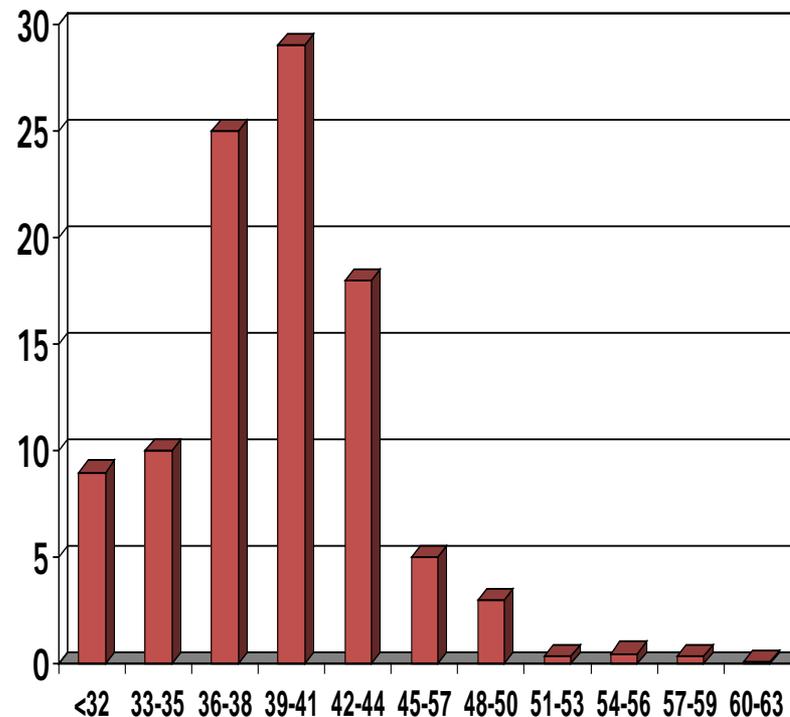
**Home Refrigerator Temperatures (°F)**

The World Is a Very Diverse Place

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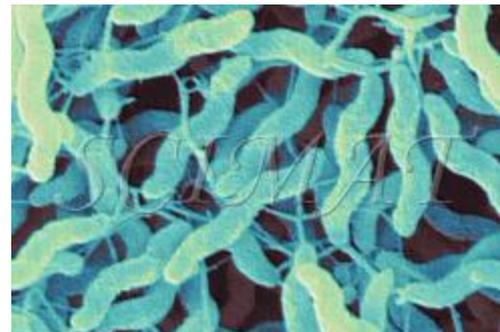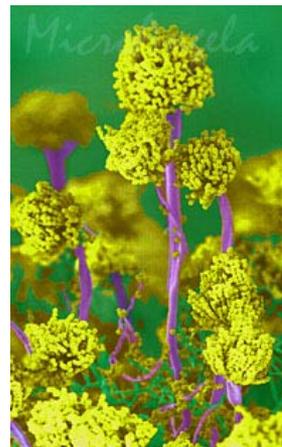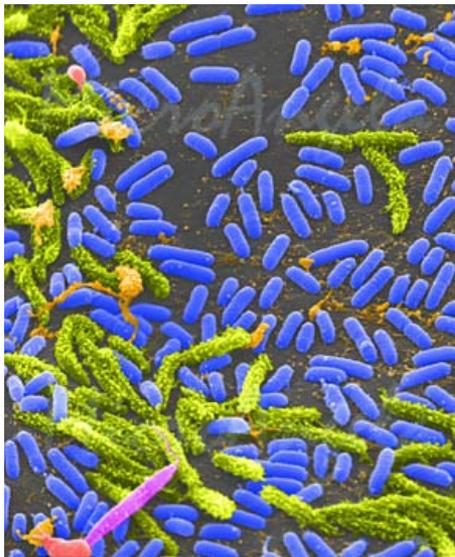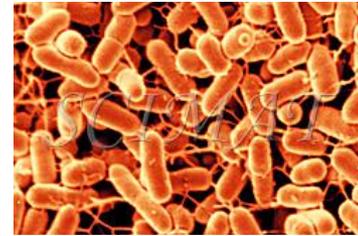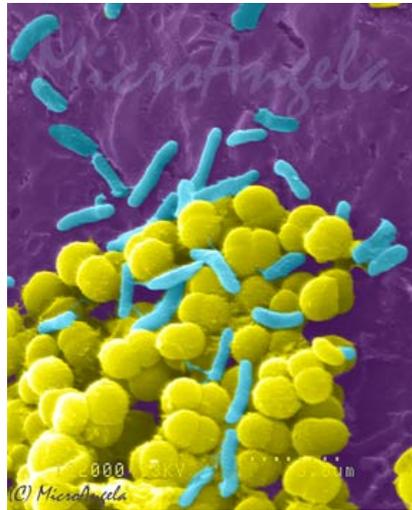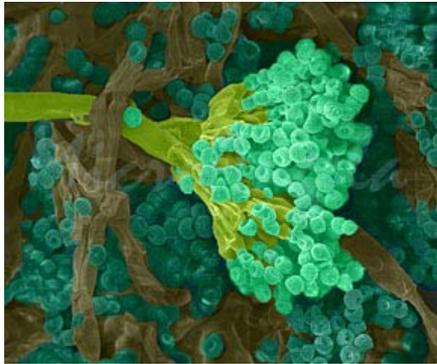
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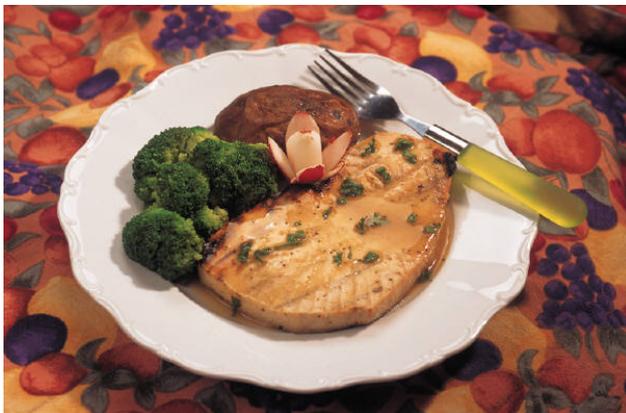
Uncertainty vs. Variability

- Uncertainty
  - Incomplete information
  - Can reduce by acquiring more information

- Variability
  - Inherent diversity of a system
  - Cannot be reduce by acquiring more information though may achieve a better estimate

Consider Variability and Uncertainty

- Try not to use single point values

- Instead try to use probablistic models which use distributions that capture variability and uncertainty

- Capture via simulation modeling
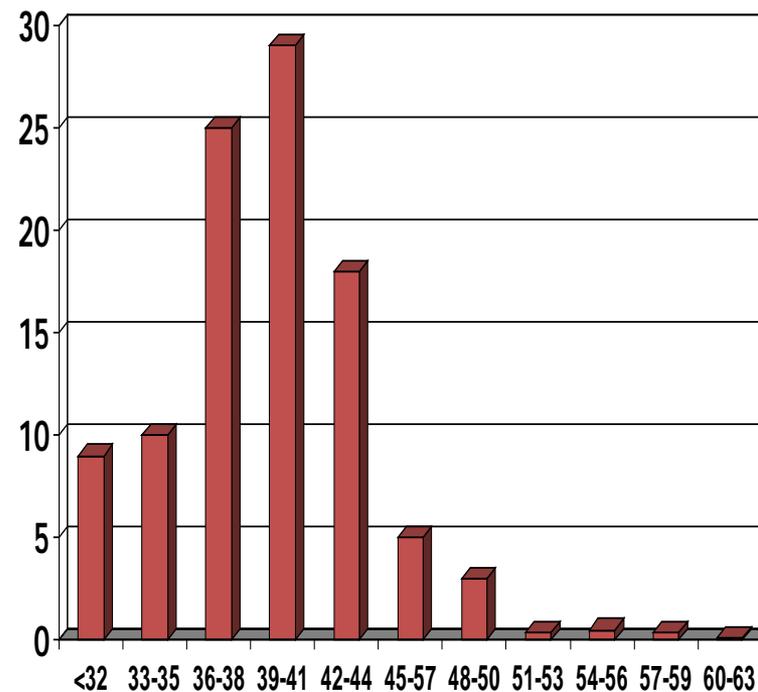
Home Refrigerator Temperatures (°F)

Probabilistic Modeling

- Use "Monte Carlo" simulations to increase the accuracy of the predictions

- Considers parameters as distributions instead of single values

- Risk managers often have trouble with probabilistic models because do not get a binary answer
  - Puts the responsibility for risk decisions clearly on the risk manager

Monte Carlo Simulation

- What number would I get if I rolled three dice?
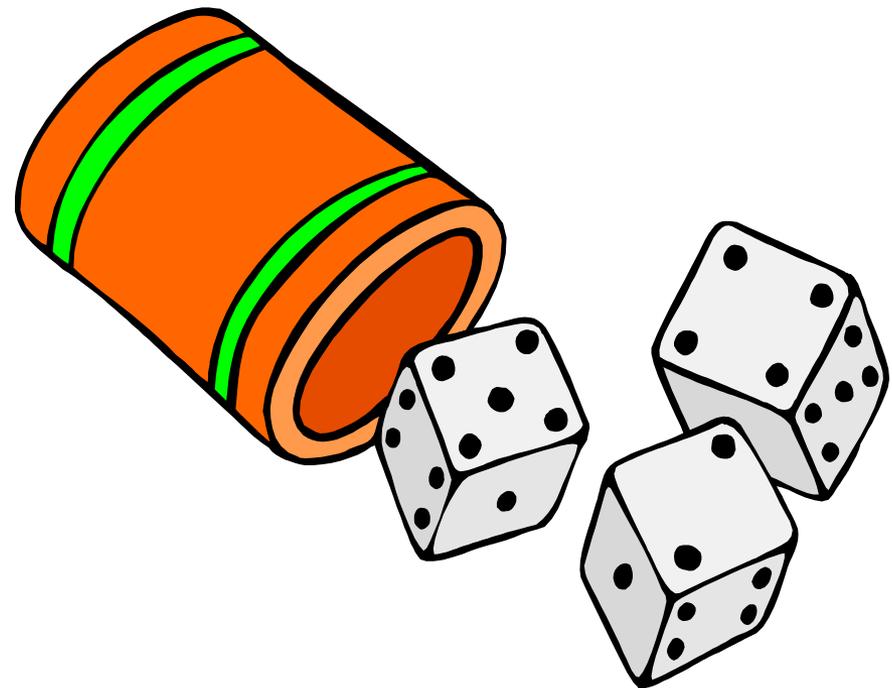
Dealing with Distributions
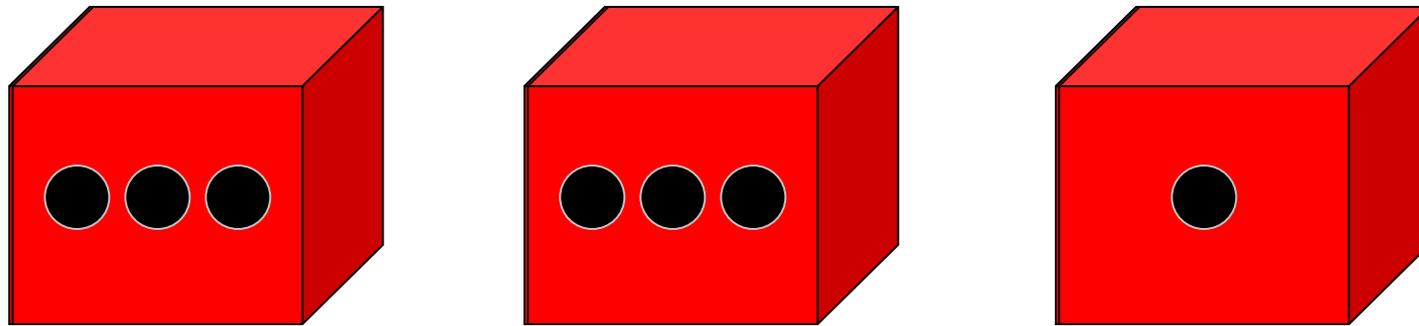
3   +   3   +   1

= 7

Dealing with Distributions
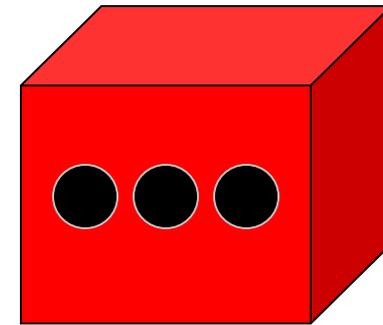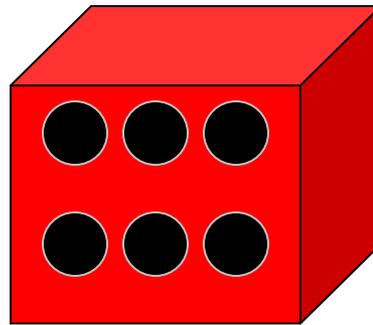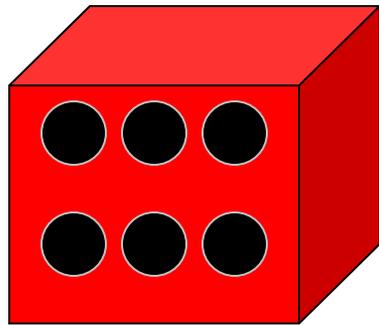
6   +   6   +   3

= 15

Monte Carlo Simulation
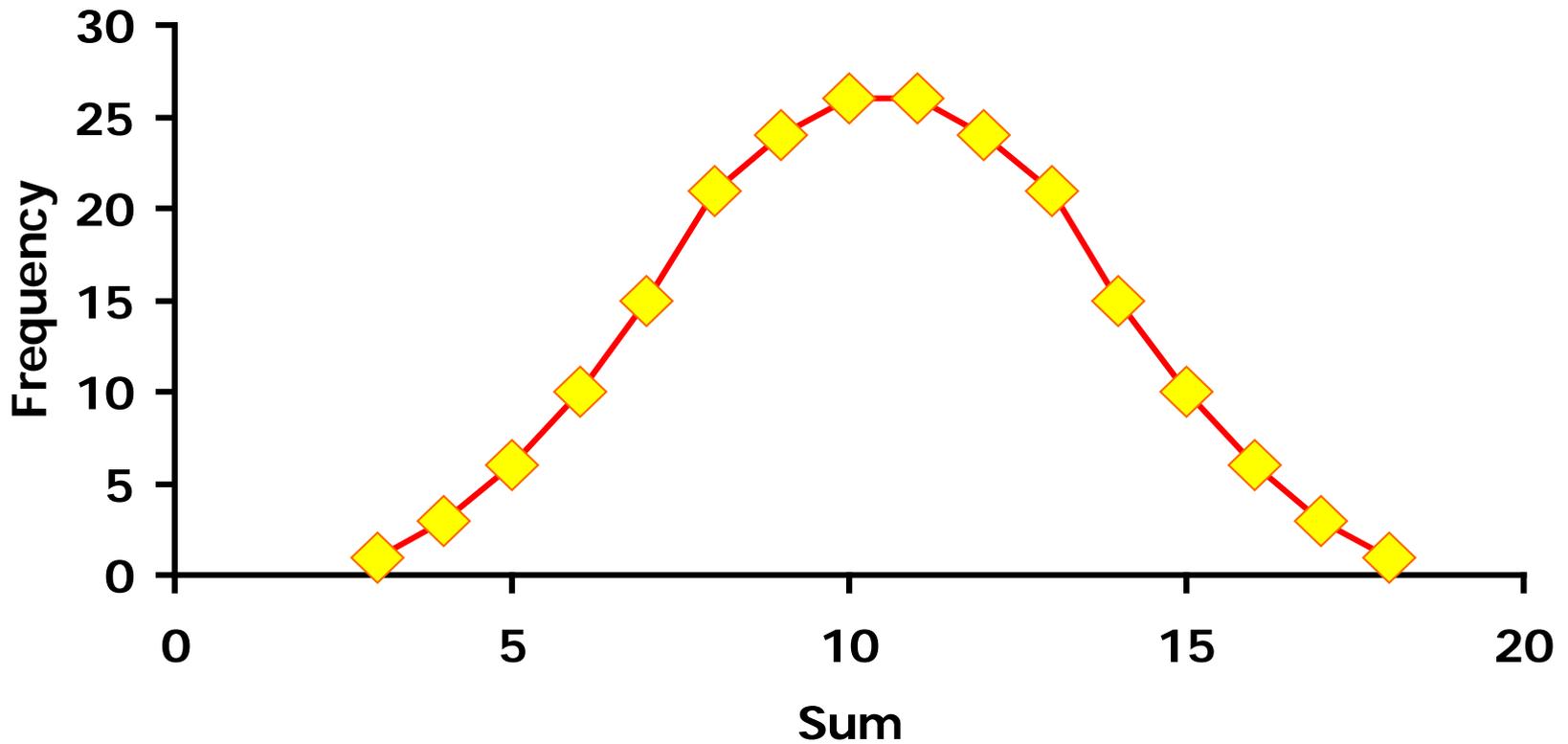
Incorporating Diversity into Evaluations

- Availability of "user friendly" software has greatly changed the ability to describe variability and uncertainty

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Food Safety Risk Assessments

- Within a risk assessment class there can be multiple forms of risk assessment; e.g. microbial risk assessments
  - Product/Pathogen Pathway
  - Risk Ranking
  - Risk/Benefit Analysis
  - Risk/Risk Analysis
  - Geographical Introduction Analysis
  - Consequence Analysis

Risk Assessment Tool 1: Hazard/Product Pathway Analysis:
Example -Cold Smoked Salmon and *Listeria monocytogenes*
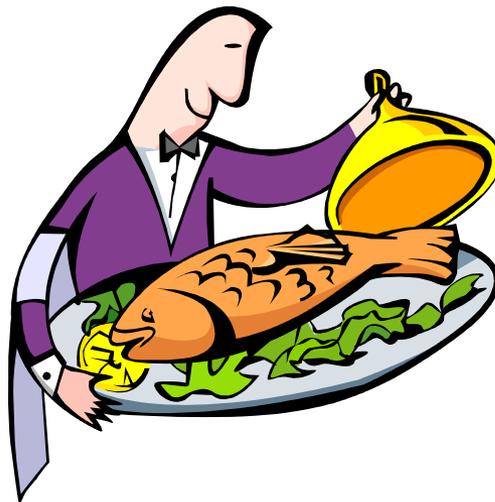
Hazard/Product Pathway Analysis

- Used in determining what are the factors along the farm to table continuum that contribute to the risk associated with a specific hazard

- Used to

  - Design food safety system to achieve risk mitigations

  - Develop risk-based standards

  - Establish monitoring and verification programs

Catch and transport

Frozen Storage → Thaw → Dehead/Gut/Split

Refrigerated Storage → Rinse → Dehead/Gut/Split

Dehead/Gut/Split → Brine → Drain

Dehead/Gut/Split → Dry Salt → Rinse

Brine → Drain → Refrigerated Storage

Dry Salt → Rinse → Refrigerated Storage

Refrigerated Storage → Rack/Equilibrate

Rack/Equilibrate → Hot Smoke

Rack/Equilibrate → Cold Smoke

Hot Smoke → Slice/Mince/Mix

Cold Smoke → Slice/Mince/Mix

Slice/Mince/Mix → Air/MAP Package

Air/MAP Package → Frozen Storage

Air/MAP Package → Refrigerated Storage

Frozen Storage → Distribution

Refrigerated Storage → Distribution

Distribution → Market

Data Needs for Exposure Assessment

- Phase I: Production Through Sale
  - Frequency and extent of contamination in raw materials and finished product, and at intermediate steps if possible
  - Growth/survival characteristics of pathogen
  - Product composition and characteristics
  - Storage times and temperatures
  - Impact of various processing steps

Data Needs for Exposure Assessment

- Phase II: Sale Through Consumption
  - How food is consumed
  - Storage times and temperatures
  - Potential contamination in home
  - Impact of preparation steps and practices

Data Needs for Exposure Assessment

- Phase III: Consumption information
  - Serving size
  - Number of servings consumed
  - Differences in consumption based on
    - Age
    - Ethnicity
    - Seasonality
    - Geography

Risk Characterization

- A: Home Storage Time
- B: Home Storage Temperature
- C: Retail Storage Time
- D: Initial Level
- E: Number of Portions Contaminated in High Hygiene Plants
- F: Temperature During Distribution
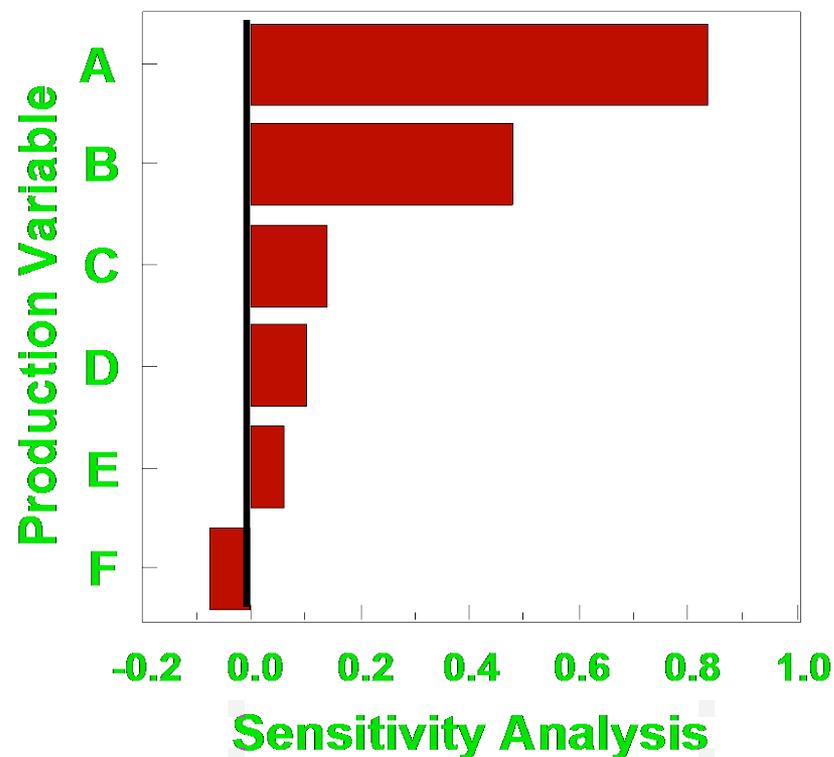
RA Tool 2: Risk Ranking

Managing Food Safety Risk

- Full table of hazards and risks

- Trying to do everything means nothing gets done well

- Regulatory agencies and industry are both finding that they need more objective tools for priority setting

Risk Ranking

- Used in U.S. for over 25 years for priority setting priority setting for environmental hazards

- Largely done as qualitative or semi-quantitative risk profiles

- Often confused risk management and risk assessment – got a tarnished reputation as a result

- Separation of risk assessment and risk management and emergence of quantitative approaches have rekindled interest

Predicted Cases of Listeriosis per Annum for Total Population
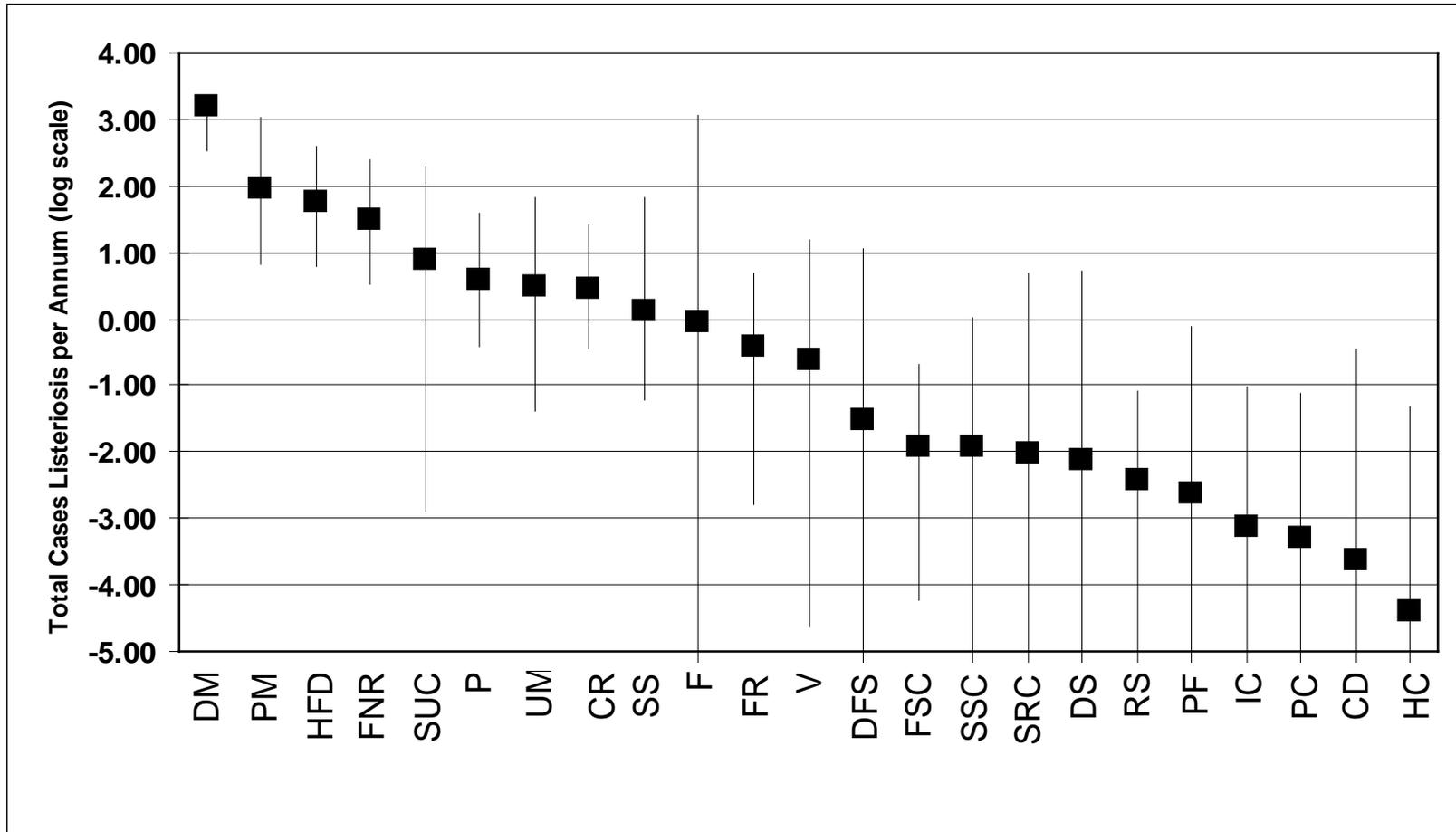
Predicted Cases of Listeriosis per Serving for Total Population

Decreased Risk per Annum →

	Clusters A and B	Clusters C and D	Cluster E	
	Very High Risk Deli Meats Frankfurters (not reheated)	**High Risk** Pâté and Meat Spreads Unpasteurized Fluid Milk Smoked Seafood	**Moderate Risk** No food categories	**Cluster 1**
	High Risk High Fat and Other Dairy Products Pasteurized Fluid Milk Soft Unripened Cheese	**Moderate Risk** Cooked RTE Crustaceans	**Moderate Risk** No food categories	**Cluster 2**
	Moderate Risk No food categories	**Moderate Risk** Deli-type Salads Dry/Semi-dry Fermented Sausages Frankfurters (reheated) Fresh Soft Cheese Fruits Semi-soft Cheese Soft Ripened Cheese Vegetables	**Low Risk** Preserved Fish Raw Seafood	**Cluster 3**
	Moderate Risk No food categories	**Low Risk** No food categories	**Very Low Risk** Cultured Milk Products Hard Cheese Ice Cream and Other Frozen Dairy Products Processed Cheese	**Cluster 4**

Decreased Risk per Serving ↓

Risk Ranking

- Can span the entire qualitative to quantitative spectrum with all the benefits and limitations of each

- Complexity increases with number of:
  - Classes of agents (e.g., chemical, microbiological)
  - Agents within a class
  - Biological end points associated with an agent
  - Food classes
  - Diversity of foods within a class
  - Diversity in susceptibility of population

Risk Ranking Risk Assessments

- Six levels based on increasing complexity
  - Level 1: Single agent in multiple food classes
  - Level 2: Single class of agents in a single food class
  - Level 3: Single class of agents in multiple food classes
  - Level 4: Multiple classes of agents in a single food
  - Level 5: Multiple classes of agents in a single food class
 - Level 6: Multiple classes of agents in multiple classes of foods

Risk Ranking

- Future success in advancing risk ranking techniques beyond level 2 is going to be highly dependent on finding a common metric that is reasonable, understandable to the public, and easy to use

    – DALY's, pseudo-DALY's

Development of Common Metrics

- Increasingly using "Disability Adjusted Life Years" for consideration of comparative risks

- Based on concept that there is an "ideal state" from which you subtract

Disability adjusted life years (DALYs) by risk factor and sex, NSW 2003

	Males	Cause	Females
Tobacco	9.6	Tobacco	5.8
High body mass	9.0	High body mass	8.1
High blood pressure	7.8	High blood pressure	7.3
High blood cholesterol	6.5	High blood cholesterol	5.9
Physical inactivity	6.5	Physical inactivity	6.7
Alcohol	3.9	Alcohol	0.6
Occupational exposures	2.7	Occupational exposures	1.3
Illicit drugs	2.7	Illicit drugs	1.2
Low fruit and vegetable intake	1.9	Low fruit and vegetable intake	1.0
Urban air pollution	0.8	Urban air pollution	0.8
Unsafe sex	0.4	Unsafe sex	0.7
Child sexual abuse	0.3	Child sexual abuse	1.4
Osteoporosis	0.1	Osteoporosis	0.3
Intimate partner violence	0.0	Intimate partner violence	2.1

Per cent of total burden

Risk Ranking Assessment

- Seeing similar comparative assessments and tools being applied to quantitative risk ranking assessment

- Recent development and release of the FDA "iRisk" software for doing comparative risk assessment tool makes it increasingly possible to do risk-risk evaluations
  - http://foodrisk.org/exclusives/fda-irisk-a-comparative-risk-assessment-tool/

RA Tool 3:
Risk – Benefit Analysis

Risk – Benefit Assessment

- There has been renewed interest in consideration of benefits in food safety decision making for chemicals similar to what is done for the approval of new drugs, biologics and medical devices

- The major argument for risk-benefit is that this would allow more "informed decisions" by putting risks in a broader societal context

Risk – Benefit Assessment

- A number of things that are likely to get in the way of that goal
  - A long history of "safety only" consideration for pre-market approvals for foods
  - Consumers' risk tolerance is much less for foods than drugs
  - Difficult to communicate how consumer benefit
  - Why consider tolerances when there is surplus production of most foods – "high avoidability"
    - Changing somewhat due to consideration of food security issues
  - Difficult to document and quantify benefits and then compare against risks

Always Remember

- A risk assessment does not provide "THE ANSWER"

- It provides information that the risk managers can draw upon to make more informed decisions