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Risk Assessment: Examples in Guiding Food Safety

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Food Safety and Inspection Service

Risk Assessment: Examples in Guiding Food Safety

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Presentation Overview

- Risk Analysis at Food Safety and Inspection Service (FSIS)
  - Overview of the US Food Safety System
  - Risk Analysis at FSIS
- Data Requirements and Sources
- Examples of Incorporating Risks into FSIS Inspection Activities
  - Risk-Based Sampling
    - *Listeria monocytogenes (Lm)*
    - *Escherichia coli* (*E. coli*) O157:H7
  - Public Health Regulations and Food Safety Assessments
  - Linking Inspection Activities to Microbial Outcomes

Risk Analysis at FSIS

FSIS' Role within US Food Safety System

- The Food Safety and Inspection Service (FSIS):
  - Public health agency in the U.S. Department of Agriculture

  Responsible for ensuring that the nation's commercial supply of **meat, poultry, and egg products** is safe, wholesome, and correctly labeled and packaged

  Overall goal is reducing foodborne illnesses from FSIS-regulated products
- Other government agencies regulating the safety of the US food supply include:
  - Food and Drug Administration, HHS
  - Animal and Plant Inspection Service, USDA
  - State and Local Agencies

Role of FSIS Offices in Risk Analysis

- At FSIS, the Risk Assessment and Analytics Staff (RAAS) within the Office of Public Health Science conducts the risk assessments
- Risk management staff is within the Office of Policy and Program Development

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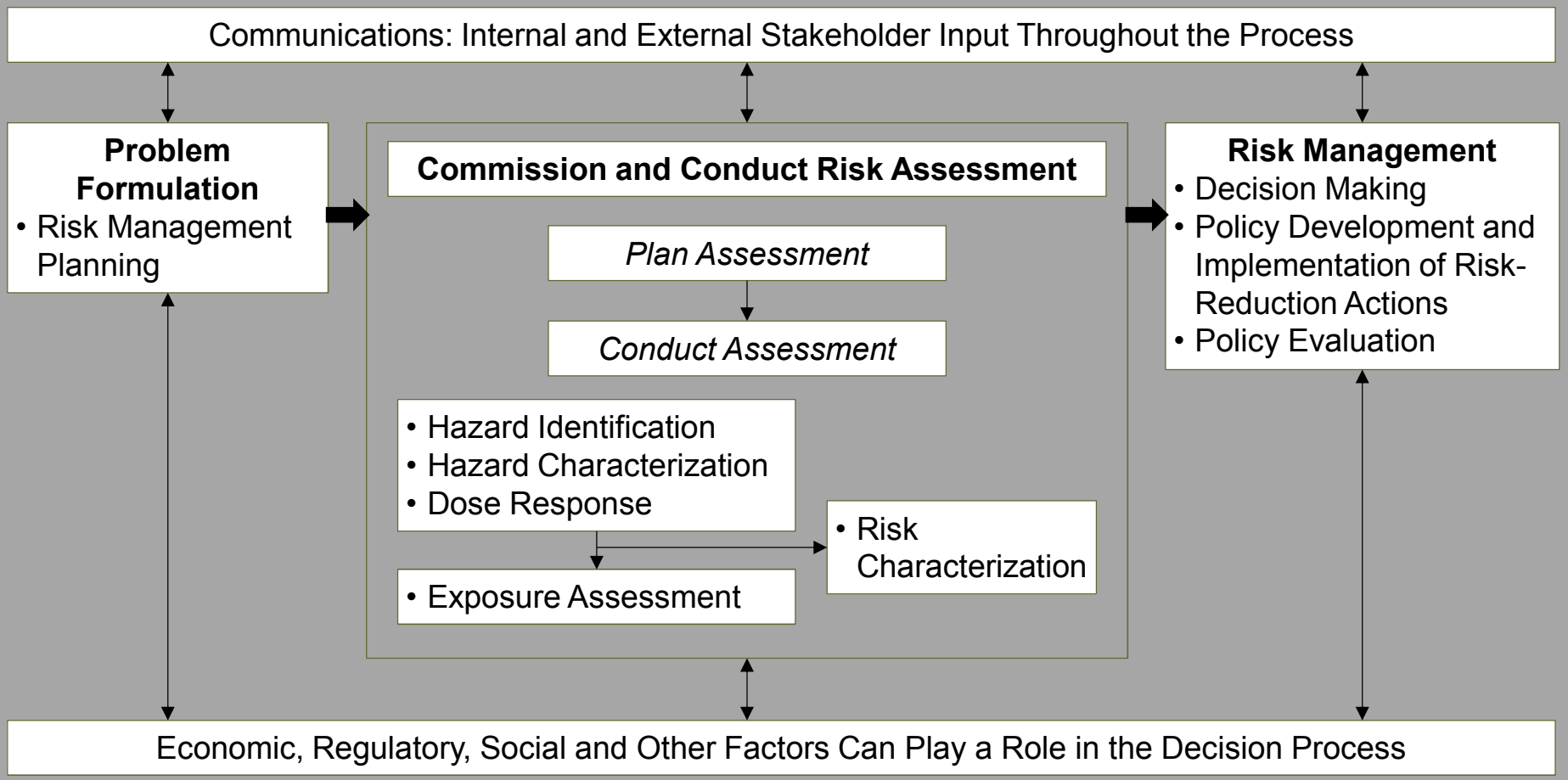
Risk-Based Decision Making Process



The Risk Analysis Process at FSIS: Problem Formulation

- Activities during this phase include:
  - Identify food safety issues
  - Establish risk management goals
  - Derive risk management options
  - Develop specific questions to be informed by data analyses (e.g., economic analysis, risk assessment, and data analyses)
- A number of reports emphasize the importance of this initial phase (e.g., Science and Decisions, NRC 2009; Interagency Microbial Risk Assessment Guidelines)
- RAAS works with OPPD risk managers and others to determine which analyses are needed to provide answers to specific risk management questions

The Risk Analysis Process at FSIS: Commission and Conduct of Assessment

- Extensive interaction among risk assessors and others at FSIS:
  - Clarify data and information needs,
  - Integrate data analysis, economic analysis and risk assessment plans (including peer review efforts)
- Analyses should be “fit-for-purpose” and choice depends on:
  - Appropriateness and quality of available data
  - Influence of analyses in decision
  - Consequences of the decision
  - Regulatory requirements
  - Time constraints
  - Resource availability
- Risk assessors must be objective, and free of potential conflicts of interest and pressure related to the assessment results

The Risk Analysis Process at FSIS: Risk Management

- Involves:
  - Selection of risk management options
  - Implementation of a risk management strategy
  - Monitoring and evaluating new or revised policies and programs to ensure risk management strategies are achieving food safety goals
- Policy leads risk management phase
- Risk assessors provide support through:
  - Any additional analyses that are needed, or evaluation of food safety strategies
  - Communicating the risk assessment approach and results, including its limitations, uncertainties and how it should be interpreted

Data Requirements and Sources

Sources of Data: Bottom-Up Assessments

- Bottom-up assessments follow agent through the steps in food production to predict the risks, data requirements might include:
  - Concentrations of contaminants at different points in production
    - FSIS data from verification samples and Baseline surveys
  - Growth curves and log reductions for different interventions
    - Published literature
  - Use of interventions by industry
    - FSIS checklists, published literature
  - Production volume
    - FSIS data
  - Consumption data
    - NHANES
  - Relationship between product contamination and human illnesses
    - Published by FSIS

Sources of Data: Top-Down Assessments

- "Top-down" (surveillance-based) assessments estimate the risk associated with specific foods and hazards using epidemiology data, data requirements might include:
  - Rate of specific illness in population of interest
    - CDC data (Scallan et al., 2011)
  - Proportion of illnesses associated (attributed) to the product of interest
    - Published literature (Painter et al., 2013)
  - Relationship between human illnesses and product contamination
    - Published by FSIS (Williams et al., 2011)
  - Consumption data
    - NHANES
  - Production data
    - FSIS, Economic Research Service or industry data

Sources of Data: Other Assessments

- Estimating the effect of potential or implemented policies or activities on illnesses:
  - Effect of interventions or FSIS activities on contamination
    - Published literature or relationships in FSIS data
  - Prevalence of interventions or frequency of FSIS activities
    - Industry data, FSIS surveys or FSIS inspection data
  - Production volume or consumption data
    - FSIS data or NHANES

FSIS Data: Public Health Information System

- FSIS' IT system launched in 2012 (replaced Performance Based Inspection System; PBIS)
- Schedules field inspector activities:
  - Sanitation tasks
  - HACCP verification tasks
  - Sampling request
  - Food Safety Assessments
- System captures data in an accessible format:
  - Regulations that inspectors are verifying
  - Results of verification activities (e.g., non-compliance records)
  - Establishment profile (e.g. production volume, products produced)

FSIS Data: Sampling Results

- FSIS verification sampling
  - *Salmonella*
  - *E. coli* O157:H7
  - Non-O157:H7 STECs
  - *Listeria monocytogenes (Lm)*
  - Residues
- FSIS Baseline studies
  - Designed to determine prevalence of and enumerate pathogens and indicator organisms, typically at two points in the food processing system

Examples of Incorporating Risks into FSIS Inspection Activities

Risk-Based Sampling *Lm*: *Purpose*

- Risk assessment conducted (May 2007) to provide guidance to implement a risk-based verification sampling program for *Lm*
  - FSIS had stated its intent to develop a risk-based sampling program that would consider the reduction in likelihood of *Lm* contamination as establishments moved from Alternative 3, to Alternative 2a or 2b, to Alternative 1.

Risk-Based Sampling *Lm*: Alternatives

- RTE meat and poultry establishment Alternatives depend on voluntary adoption of post lethality processing, antimicrobial agents, and/or sanitation procedures.
  - Alternative 1 establishment: uses a post-lethality treatment (PLT) to reduce or eliminate *Lm* in product and an antimicrobial agent or process (AMAP) to limit or suppress growth of *Lm* in product
  - Alternative 2 establishment:
    - 2a: uses a PLT to reduce or eliminate *Lm* in product
    - 2b: uses an AMAP to limit or suppress growth of *Lm* in product
  - Alternative 3 establishment: relies on sanitation alone to prevent *Lm* in processing environment and on product

Risk-Based Sampling *Lm*: *Approach*

- Goal to develop risk ranking algorithm that includes only risk factors with a quantitatively defined relationship to *Lm* contamination:
  - information on type of product processed
  - the volume of production self-reported via census form
  - past 6 month history of FSIS sample results
- Classified products into three categories (deli meat, frankfurters and other RTE products) used for the Risk Ranking model
- Volumes of the three different product types were converted into an equivalent volume of deli meat, which was multiplied by an Alternative-Volume-specific risk factor
- That risk score rank modified up or down, based on individual establishment's historical sampling results

Risk-Based Sampling *Lm*: *Results*

- Rank all establishments making post-lethality exposed RTE products according to public health risk
- FSIS schedules sample collection according to this risk ranking monthly
- Allows FSIS to target finite resources at those establishments that are most likely to produce contaminated product
- Provides incentive for establishments to adopt effective *Lm* control measures

- Note – with launching of PHIS, some data categories for *Lm* changed and the algorithm had to be adjusted to incorporate the changes

Risk-Based Sampling *E. coli* O157:H7 in Ground Beef: Purpose

- In 2008, FSIS developed a risk-based algorithm for sampling *E. coli* O157:H7 in ground beef
- Objectives:
  - Increase the proportion of samples taken at establishments that are more likely to produce product contaminated with *E. coli* O157:H7
  - Allocate FSIS resources more efficiently by verifying a greater portion of the U.S. ground beef supply with the same number of samples as the current program
  - Verify all eligible establishments at a reasonable frequency regardless of an establishment's production volume, interventions, or predicted public health risk associated with their product

Risk-Based Sampling *E. coli* O157:H7 in Ground Beef: Approach

- Data considered:
  - FSIS *E. coli* O157:H7 (ground beef) sample results
  - Production volume
- Principles:
  - Every establishment eligible for testing of raw beef is placed in a sampling frame each month
  - Each establishment in the sampling frame is assigned a portion of the probability "space" from 0 to 1
    - The higher an establishment's potential to cause *E. coli* O157:H7 illness, the larger the space.

Risk-Based Sampling *E. coli* O157:H7 in Ground Beef: Approach

- Algorithm computes two scores:
  - Volume Score: calculated for each establishment category based on the average amount of product produced per day
  - Hazard Score: determined by the *E. coli* O157:H7 test results.
    - If an establishment has tested positive within the last four months, the hazard score is 5. Otherwise it is 1
- Sampling restrictions:
  - Ceiling: No more than 4, 3, 2, or 1 samples per month based on size
  - Floor: Every establishment must receive 3 analyses per year
- Product of the two scores is used to calculate the individual sampling probability for each establishment

Risk-Based Sampling *E. coli* O157:H7 in Ground Beef: Approach

- Establishments not meeting the floor in the past 12 months are selected with certainty
- Random number generator selects numbers between 0 and 1. If the number is within an establishment's space, and the establishment has not exceeded its ceiling, the establishment is selected for sampling
  - The larger an establishment's probability space, the greater the chance it will be selected
- The algorithm selection of an establishment ("draw") is random. In each draw, each establishment has a chance of being sampled; but the probability of being selected is dictated by the potential public health risk

Risk-Based Sampling *E. coli* O157:H7 in Ground Beef: Future Considerations

- FSIS continues to review the available data and considers ways to update its sampling algorithm to optimize its sampling programs
- Other information that could be considered to direct sampling:
  - FSIS surveys on establishment practices
  - Seasonality

Public Health Regulations and FSAs: Purpose

- To use FSIS inspection activity results to prioritize Food Safety Assessments (FSAs)
- FSAs are conducted by FSIS' Enforcement, Investigations and Analysis Officers, who are trained to assess the design and validity of food safety systems using an FSA tool
  - consists of a series of questions that EIAOs are to help gather information associated with a specific food safety system component, and include a general sanitation tool; individual HACCP processing category tools; a dual jurisdiction tool; and a food defense tool.

Public Health Regulations and FSAs: Approach

- Public Health Regulations (PHRs)
  - Regulations that have significantly higher noncompliance rates 3 months before a *Salmonella*, *E. coli* O157:H7, or *Lm* positive
- PHR list comprised of 33 regulations, e.g.:
  - Failure to maintain adequate HACCP Plan
  - Failure to keep CCPs under control
  - Failure to prevent insanitary conditions
  - Failure to take appropriate corrective action
- PHRs are one criterion in prioritizing scheduling FSAs
- Noncompliance with a single PHR regulation does not indicate loss of process control

Public Health Regulations and FSAs: Approach

- Separate establishments into
  - Slaughter only,
  - Processing only and
  - Slaughter plus Processing
- Identify establishments that significantly deviate from the 3-month rolling average noncompliance rate for all similar establishments using aggregate set of PHRs
- Two cut points for each of the three plant types divide each plant type into three groups that receive different priorities for FSA scheduling:
  - Mean PHR rate plus *one* standard deviation
  - Mean PHR rate plus *three* standard deviations

Public Health Regulations and FSAs : Approach

Compute establishment PHR NC rate

Compare to cut point for similar establishments

If selected, include in proposed FSA schedule

District Office selects FSAs to perform

Linking Inspection Activities to Microbial Outcomes: Purpose

- Identify the public health impact of different FSIS inspection activities in poultry slaughter facilities

FSIS Microbiological Data

Data from FSIS Inspection Activities

Step 1
Estimate the Relationship between establishment variations in FSIS-Inspection Activities and frequency of *Salmonella* and *Campylobacter* positives on Poultry carcasses

Previous Estimates
Relationship between *Salmonella* and *Campylobacter* Contamination on poultry and human illness.

- Uses CDC data and FSIS analyses

Step 2
Predict the Effect of Increasing Specific Inspection Activities Using the Relationship Estimated in Step 1

- Predictions are made for scenarios ("what ifs") with a range for the number of the four different inspection procedures (SP, SNP, U and NC)
- Scenarios are based on the number of the different procedures performed in HIMP vs non-HIMP poultry establishments

OUTPUT

Estimated Annual Number of Illnesses from *Salmonella* and *Campylobacter* under different inspection scenarios
(for example, increased off-line inspection tasks)

Linking Inspection Activities to Microbial Outcomes: Data Sources

- Inspection activities data from FSIS' PBIS database
- *Salmonella* and *Campylobacter* prevalence data for the same establishments and timeframes as PBIS data:
  - FSIS Young Chicken Baseline study
  - Chicken PR/HACCP *Salmonella* verification program
  - FSIS "Young Turkey Baseline"
  - Turkey PR/HACCP *Salmonella* verification program
- Number of human *Salmonella* and *Campylobacter* illness attributable to young chicken and turkey consumption estimated from CDC total foodborne illness and outbreak data

Challenges

- Data availability
  - FSIS Microbial data
    - Sample numbers for some product-pathogen pairs
    - Lack of power to detect associations when number of positives is very low
  - Use of interventions by industry
  - Epidemiology and outbreak data
- Data quality
- Communicating risk assessment results
  - Internally and to stakeholders

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Questions?

FSIS Risk Assessment Website:
http://www.fsis.usda.gov/wps/portal/fsis/topics/science/risk-assessments

Website with Notice describing Public Health Regulations for use in Scheduling FSAs:
http://www.fsis.usda.gov/wps/wcm/connect/14d1c532-3b99-4bca-8f0d-1f59b738d4f7/63-13.pdf?MOD=AJPERES