

Food Attribution: Critical Data for FDA's Regulatory Programs

Robert L. Buchanan, Ph.D.

HHS Food and Drug Administration

Center for Food Safety and Applied Nutrition



FDA Regulatory Programs

- FDA/CFSAN is committed to maintaining and building upon its international reputation as a risk-based, science-led food safety agency
- Better knowledge of food attribution is a critical resource for our meeting that goal

FDA Regulatory Programs

- Continually striving to be an organization that is
 - Public health oriented
 - Science-based
 - Risk-based
 - Cost-effective
 - Proactive
 - Responsive
 - Learning and self-correcting
 - Continuously improving
- Achieving these goals is a very data intensive process

FDA Regulatory Programs

- **Data needed to**
 - Establish scientifically sound standards and guidance
 - Determine base-line inspection rates and approaches
 - Highest risk foods
 - Import vs. domestic foods
 - Seasonality
 - Regional differences
 - Design better education/outreach programs and food labeling approaches

FDA Regulatory Programs

- **Data needed to**
 - Determine where in the “farm-to-table continuum” are the likely sources of contamination and the most effective points for mitigation
 - Differentiate food safety concerns due to inherent risk vs. compliance failure
 - Establish the equivalence of different food safety systems

Defining Food Attribution?

Defining Food Attribution?



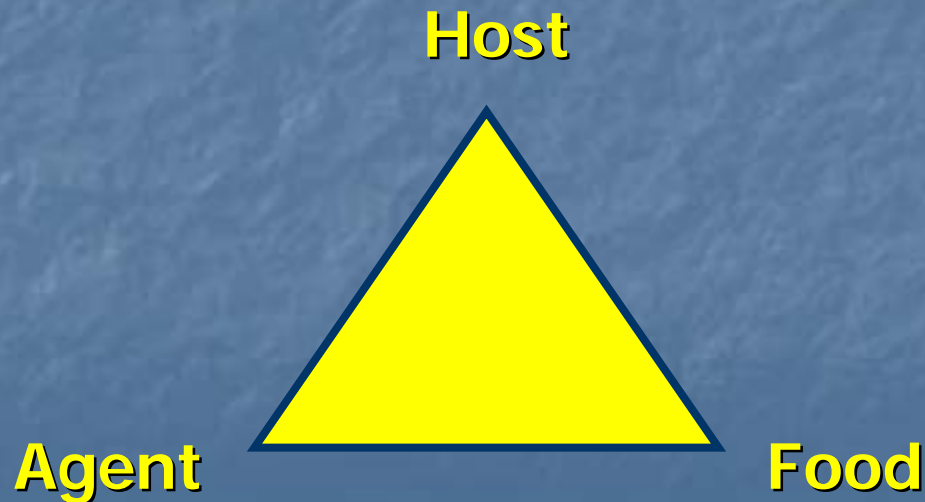
Defining Food Attribution

- Take a broad view of food attribution
- The information needed to understand who is getting sick and why?



Defining Food Attribution

- In its most general sense, it is the information needed to define the disease triangle
- Understanding diversity is critical part of developing sound food safety policy



Food Attribution Data

- Main sources of food attribution data
 - Host
 - Outbreak data
 - Sporadic case data
 - Annual disease statistics
 - Food consumption surveys
 - Consumer practices surveys
 - Food
 - Microbiological baseline studies
 - Outbreak data

Food Attribution Data

■ Need to know

- Who gets sick? Who doesn't get sick?
- What foods are involved?
- Where did the foods come from?
- What was done to the foods?
- What are the contributing factors that lead to foodborne illness?
- Was it an inherent risk or a failure?
- What was the frequency and level of contamination of the food?
- Did the consumer know what to do with the food?
- Etc

Becoming More Important As Risk Assessment Becomes Way of Doing Business

- Increasingly important as a formal consideration of risk becomes a way of doing business
 - **Nationally**
 - Executive Order
 - Information Quality Act
 - **Internationally**
 - WTO
 - Codex Alimentarius

Examples of Food Attribution Activities

- “FDA/FSIS Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods”
 - Frequencies and levels of contamination in retail foods
 - Foods associated with sporadic cases and outbreaks of listeriosis (national and internationally)
 - Annual disease statistics for
 - Immune status of population
 - Food consumption patterns
 - Characteristics of handling practices for variety of RTE foods

Examples of Food Attribution Activities

- **National Antimicrobial Resistance Monitoring Program (FDA/CDC/FSIS)**
 - Antimicrobial resistance of selected enteric bacteria isolated from foods and animals
 - Antimicrobial resistance of selected enteric bacteria isolated from humans
 - Impact of antimicrobial resistance on ability to treat human disease
 - Potential linkage between food/animal isolates and human isolates

Examples of Food Attribution Activities

- “Quantitative Risk Assessment on the Public Health Impact of Pathogenic *Vibrio parahaemolyticus* in Raw Oysters”
 - Sporadic cases and outbreaks of *V. parahaemolyticus* gastroenteritis
 - Percentage of cases attributable to raw oysters
 - Frequency and concentration of *V. parahaemolyticus* in marine environment and oysters
 - Sources of oysters vs. location of illness
 - Immune status of patients
 - Percentage of pathogenic strains of *V. parahaemolyticus*
 - Distinguishing oyster cases from other sources

Examples of Food Attribution Activities

- **Assessment of the public health significance of acrylamide as a contaminant in cooked foods**
 - Frequency of adduct formation in NHANES samples as a measure of exposure
 - Food survey work measuring acrylamide levels in variety of baked goods, fried foods and beverages
 - Relationship between acrylamide levels and degree of cooking
 - Relating animal toxicity data to human exposures
 - Any incidence of acrylamide related adverse effects

FDA Food Attribution Challenges

- FDA faces challenges in acquiring data due to magnitude of the food industry
 - Estimated 50,000+ food products
 - Estimated 310,000+ manufacturing facilities
 - 130,000+ domestic
 - 180,000+ foreign
 - Global nature of food industry
- Sporadic cases are more difficult to capture
- Diseases due to unknown causes still make up a significant portion of reported adverse events

FDA Food Attribution Challenges

- FDA needs in food attribution are broad and diverse
- Remain committed to working with both our sister agencies and our stakeholders to find solutions to the challenges we are facing

