Development of an Interagency Guidance Document on Microbial Risk Assessment

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OBJECTIVES OF THE MRA GUIDANCE

- Introduce uniformity across the government
- Improve consistency
- Leverage limited resources
- Foster interagency cooperation
- Improve transparency

History of Document Development

- December 2002 MRA Colloquium
- Follow-up steering group meetings – 2003
- SPC approval of proposed work – 2004
- OW – ILSI efforts: protocol workshops
- CENR Briefing March 2004 – collaboration
- Work group formation
  - –EPA programs, R&D, regional offices
  - –USDA, FDA, DoD, CDC invited
  - –Facilitated by EPA Risk Assessment Forum

Table of Contents

Introduction

- Background information
- Roles and responsibilities of key personnel
- Paradigms and frameworks
  - –Structured around the ILSI/EPA MRA framework
- Components of a risk assessment
- Contrasts chemical with microbial risk assessment

Planning and Scoping

- Defines planning and scoping
  - –Determine objectives, level of effort, resources
- Addresses Problem Formulation
  - –Aspects of problem formulation
    - Identify “valued entity”
    - Conceptual model
  - –Whom to include (RAs, RMs, Stakeholders, RC)
- Benefits
  - –Establish timelines
  - –Agree on approach
  - –“Better” decisions and easier communications

Hazard Identification

- Association between stressor and outcome
  - –Epidemiological, clinical, surveillance, microbial properties
- Discusses prospective and retrospective assessments
- Identification methods
  - –Cultural, genetic characterization
- Mode of action

Hazard Characterization/Dose Response

- Discriminates between HI and HC
  - –Emphasis on the interaction of host, stressor and environment/medium
  - –Addresses sensitive populations/life stages
- Dose response
  - –Test data (dosed, epidemiological)
  - –Selection of model (beta, Weibull, exponential)
- Transmissibility
- Broader perspective of disease and implications

Exposure Assessment

- Provides general concepts
- Recaps concepts addressed in Problem Formulation
  - –Population of interest
  - –Routes of exposure
- Probabilistic methods
- Approaches to exposure modeling
  - –Attribution and process modeling
- Model analysis

Risk Characterization

- Hazard vs. Risk and other terms
- Integration of exposure and hazard characterization
  - –Qualitative aspects
  - –Quantitative aspect

Risk Management and Risk Communication

- Roles of RA, RM and RC
- Risk Management
  - –Consequence and probability
  - –Inputs into the decision process
- Risk Communication
  - –Role of the RA and RM in RC
  - –Identifying the audience
  - –Shaping the content.