RISK CHARACTERIZATION WORKING GROUP

Risk Characterization of Acrylamide

- Is it unique? Does it warrant a different approach?
  - – Wide Exposure
  - – “Holistic”
  - – Tradeoffs
  - – Risks/Benefits
- Why?
  - – To better inform choices
  - – To communicate current state of knowledge

Characterization of Hazard

- Toxicological endpoints
  - What is known
  - What isn’t known
  - Animal/epidemiological data
- ADME similarity/differences between species
  - Chosen species

Characterization of Exposure

- Average and high consumers
- Sources of information
- Other sources of exposure?

Quantify Risk/Dose-Response – Non-cancer

- Acute Toxicity
- Multiple endpoints
    - Identify most sensitive endpoint
    - What number is the best?

Quantify Risk/Dose-Response – Cancer

- Multiple estimates
  - Different data e.g., tumor sites/types
  - Different models
    - Linear
    - Non-linear
    - Margin of Exposure
- Scientific support for different estimates
  - Best estimate versus most conservative
- Margin of Exposure

Characterize Uncertainty

- Hazard identification
  - – Mode of action – relevance to humans?
  - – Other endpoints (heritable risk, developmental and reproductive toxicity)
- Exposure
  - – Uncertainty in mean and percentiles
  - – Bioavailability
- Risk Estimate