

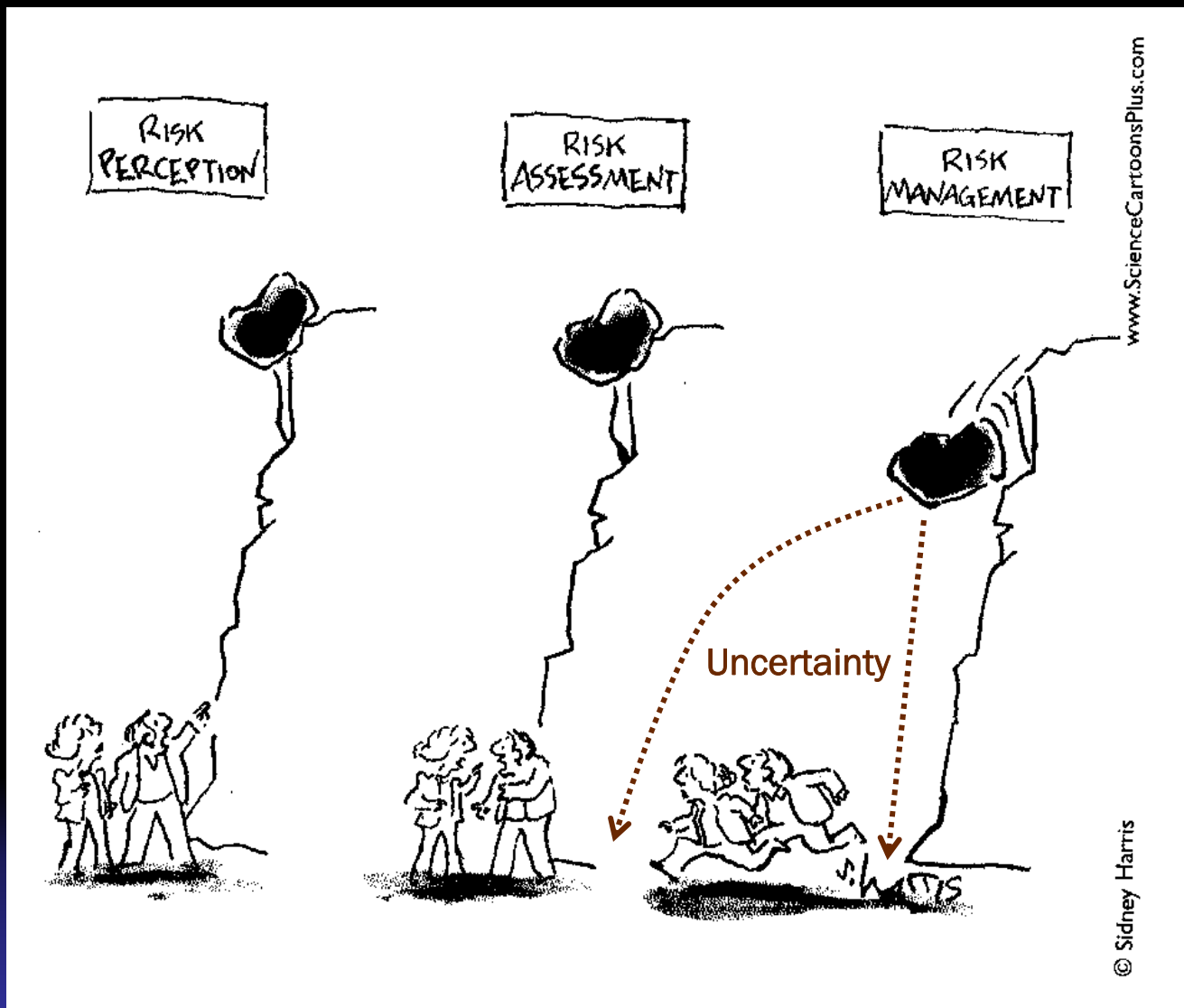
Risk Management When Benefits Are at Risk

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If it were this simple...





“Risk”

- A potential negative consequence
 - “People could be impacted by contaminants”
- Of some specified severity (magnitude of loss)
 - To health (non-cancer, cancer)
 - To economic, social, or cultural systems
- With some uncertainty about it actually happening
 - Where probability is one measure of uncertainty
 - ✚ Probability that exposure and dose-response will collude to increase the chance of an adverse health outcome
- $\text{Risk} \approx f(\text{consequence, magnitude, uncertainty})$



Risk Management

- Acceptable risk problems are decision problems
- Problems which require a choice among alternative courses of action
- Where at least one course includes a threat to life or health among its consequences
- Where choosing an alternative is facilitated by knowledge of its full set of relevant positive and negative consequences



Risky Fish

- Fish consumption offers risk and benefits
 - Risk from contaminants
 - Benefits from fatty acid consumption, recreational opportunities, and fulfillment of cultural needs
- Advisory must therefore manage for risk greater than zero, lest benefits be unnecessarily sacrificed
- So decision makers must understand
 - Consumption limits and their estimation
 - Policy and technical allowances for uncertainty
 - Discussion of risk-benefit tradeoffs with stakeholders



Questions for the Risk Manager

- How certain are you that an advisory will minimize adverse health outcomes from fish consumption, while preserving some or all benefits related to such consumption?
- What techniques are used to reduce uncertainty in consumption limit calculations?
- How might use of these techniques affect your decision and perhaps interfere with obtaining benefits from fish consumption?



Limits for Non-Carcinogens

$$CL_{nc} = \frac{\text{Reference Dose} \times \text{Body Weight}}{\text{Tissue Concentration}}$$

- CL_{nc} is NOT about risk (probability) - only a yes or no
- Reference dose is down-shifted from a NOAEL by uncertainty and modifying factors
 - Thus exceeding it does not mean an adverse health effect will occur or is necessarily more likely
 - Only that these allowances for uncertainty have been eroded



Limits for Carcinogens

$$CL_c = \frac{\text{Acceptable Risk Level} \times \text{Body Weight}}{\text{Cancer Slope Factor} \times \text{Tissue Concentration}}$$

- CL_c is “risk-based” in that allowable uncertainty is explicit as the acceptable risk level
 - This level is purely a policy choice, not science
 - Risk level is for excess risk - that in addition to the background cancer incidence rate (25-33%, all cancers)
- Cancer slope factor is a 1-hit model extrapolation down-shifted to the 95th percentile LCL

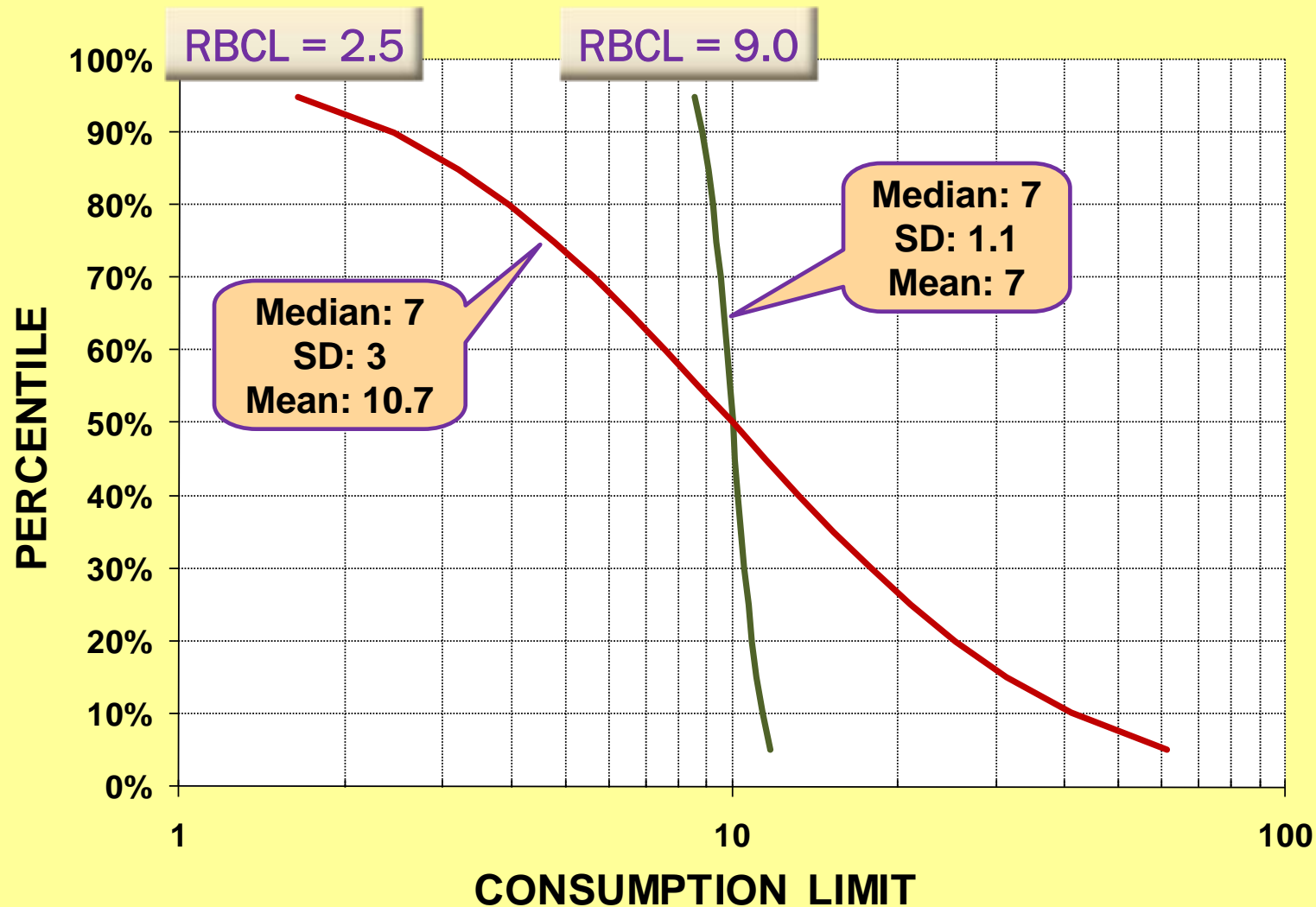


Tissue Concentration

- Major source of uncertainty
 - As stochastic variability + lack of knowledge
- Number & time/space distribution of samples
 - Lack of knowledge - too few samples too few places
- Appropriate species?
 - Stochastic variability - individual fish will always vary
 - Different species uptake pollutant in similar manner?
- Representation of value
 - Data usually have lognormal distribution
 - Arithmetic mean (>50th percentile) versus median (50th)



Impact of Concentration Variance





Suggestions

- #1! Build trust & communication with stakeholders
- Read Fish Advisory Guidance Volume III
 - Suggests opportunities for management flexibility
- Consumption limits already allow for uncertainty
 - No necessary to add more
 - Re-consider cancer or an acceptable cancer risk $>10^{-6}$
- Emphasize characterization of tissue concentration
 - Sample to minimize variance
 - Check representativeness of species sampled
 - Consider median in addition to or in place of average