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Confronting Emerging Risks

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Office of Research and Development

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Overview

- What is an emerging risk?
- New science
- New methods
- Moving forward

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Emerging Risks?

- New science or new calls for regulation?
- Does attention and advocacy keep an issue "emerging?"
- Different response with science and advocacy?

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BPA – An “emerging issue?

- Estrogenicity known since 1930’s
- Many reviews come to similar conclusions
  - EFSA
  - FDA draft
  - National Toxicology Program
  - Health Canada
- Continuing calls for further attention

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What is Emerging

- Advancing Science
- New Risk Assessment Applications
- The Need for New Approaches

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Science

- New scientific fields and methods will drive the evolution of risk analysis methods.

- For example:
  - nanotechnology
  - microbiology
  - computational toxicology

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Emerging Science - Nanotechnology

- Environmental benefits
  - Stronger and lighter materials
  - Enhanced environmental treatment and remediation
  - Improved sensing and monitoring
  - Efficient industrial processes with reduced material and energy requirements and less waste

- Challenges
  - Identify properties of possible concern (*e.g.*, fiber length)
  - Detecting/measuring particles in the environment
  - Assessing exposure: producing realistic scenarios

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Nanomaterial Risk Assessment

- Balance risks and benefits (how to define “precaution”?)
- Lifecycle approach to exposure and risk management
- “Safety by Design” – How to engineer-out properties of concern while retaining beneficial properties and material functionality? – how to trade off “safety” with function?
- Early attempt – DuPont and Environmental Defense Fund

“follows a traditional risk-assessment paradigm similar to those used by regulatory agencies to evaluate chemicals.”

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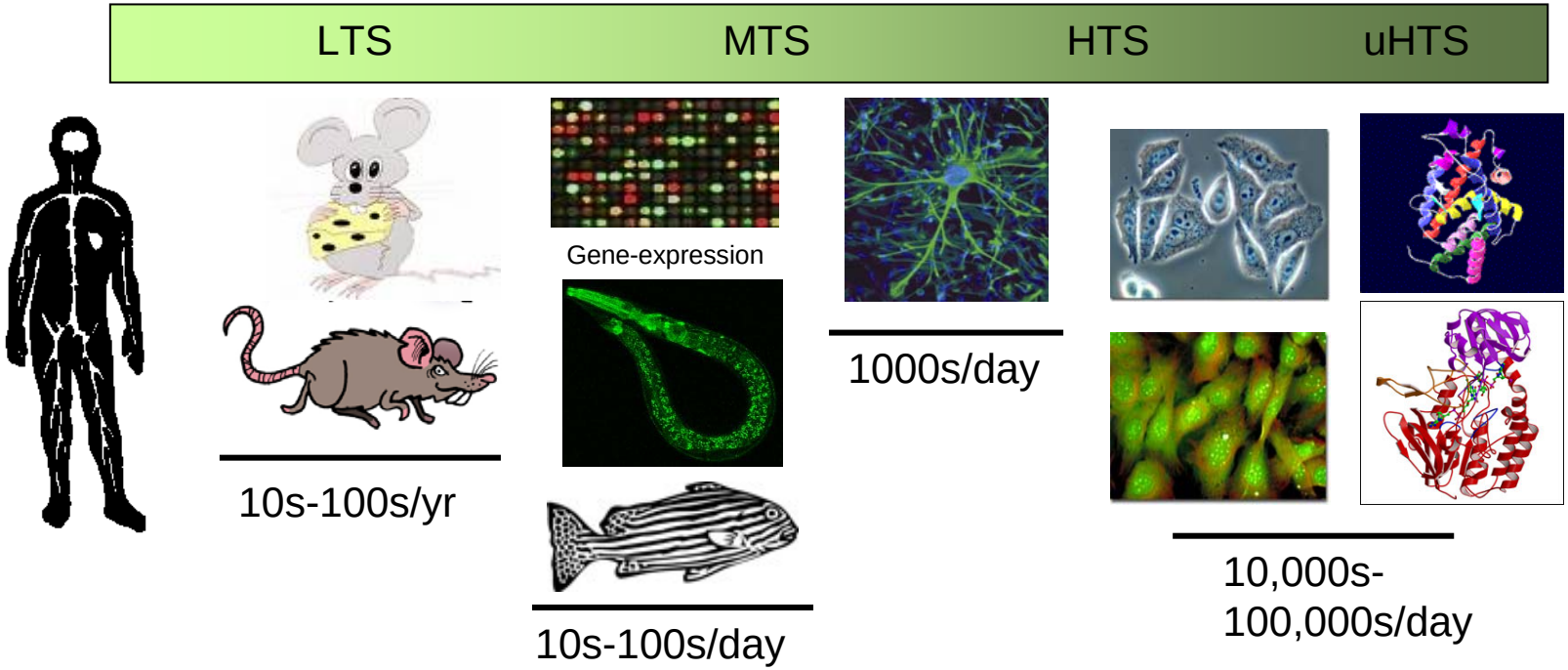
Emerging Science - Genomics

- Emerging new tools for assessing hazard
- Applicable to a wide range of stressors (chemical, biological, mixtures)
- Raise important questions for assessing risk
- Opportunity for international cooperation? Easier to agree on something new than to revise something “set in stone”

High-Throughput Screening Assays

batch testing of chemicals for pharmacological/toxicological endpoints using automated liquid handling, detectors, and data acquisition



Human Relevance/
Cost/Complexity

Throughput/
Simplicity

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Risk Analysis Challenges – Genomics

- What is an adverse effect?
- How to understand variability?
  - across species
  - within species
- Estimating the likelihood of an outcome
- Personalized risk?

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Emerging Risk Assessment Applications

- Early risk assessment focused on standard setting

- Now asking questions that involve tradeoffs
  - MeHg and fish consumption advisories
  - Disinfection by-products and microbial pathogens
  - Homeland security
  - Climate change strategies (e.g., biofuels)
  - Weighing benefits and costs

How Hazardous?

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Two Key Issues

- Cumulative risk
- Uncertainty in estimates of risk

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Cumulative Risk

- Characterization of significant sources of similar risk may be important for risk management
- Cumulative risk approaches have been pioneered for pesticides with development of specific models and guidance
- Need development for other risks

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Considering Cumulative Risk

- Where are boundaries?
  - natural/background sources of risk?
  - cumulative contributors across agency boundaries

- May be important in new applications as decision makers asked about “meaningful opportunity to reduce risk” in one arena when multiple sources contribute

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Uncertainty Analysis: When does uncertainty matter?

- When we are confronted by tradeoffs
- When it is differential across risks
- When there are real dangers to making the wrong choice

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Why Quantify Uncertainty? – Better Comparisons

- Numbers, especially single point estimates, may hide important differences between compounds
- Standard assumptions and methods of risk assessment are more scientifically plausible for some risks than for others
- Degree of conservatism in estimates varies between risks
- It is the scientifically "right" thing to do

…the SAB strongly recommended the development of methodologies for quantitative uncertainty and variability analyses of toxicological parameters such as cancer unit risk values and reference doses.

SAB Memo to Administrator Stephen L. Johnson – Science and Research Budgets for the U.S. Environmental Protection Agency for Fiscal Year 2007; An Advisory Report by the Science Advisory Board. March 30, 2006

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Moving Forward – Key Challenges

- Demonstrating methods
- Using wide range of data
- Addressing model uncertainty
- Concern about loss of “health protective” approach
- Communicating uncertainty

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Supporting Decisions

- NAS/IOM - *Environmental Decision Making Under Uncertainty*

"Based upon available literature, theory, and experience, the committee will provide its judgment and rationale on how best to use quantitative information on uncertainty in the estimates of risk in order to manage environmental risks to human health and for communicating this information"

http://www.iom.edu/CMS/3793/50520.aspx

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Summary

- New areas of science will drive new risk analysis approaches
- Enhancing risk analysis practices will better support the many different risk management challenges EPA confronts
- It is important for EPA to stay on the forefront of risk assessment practice
- Many efforts are underway to develop, demonstrate and use state-of-the-art risk assessment practice

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Thank You!