Risk Perceptions and Analyses

NIRT: Evaluating Oversight Models for Active Nanostructures and Nanosystems: Learning from Past Technologies in a Societal Context

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NIRT Research Goals & Methodology

1. Assessment of 6 oversight models utilizing criteria (literature collection and analysis, expert elicitation, consensus):
   - drugs
   - medical devices
   - **chemicals in the environment***
   - **chemicals in the workplace***
   - gene transfer research ("gene therapy")
   - genetically engineered organisms in the food supply

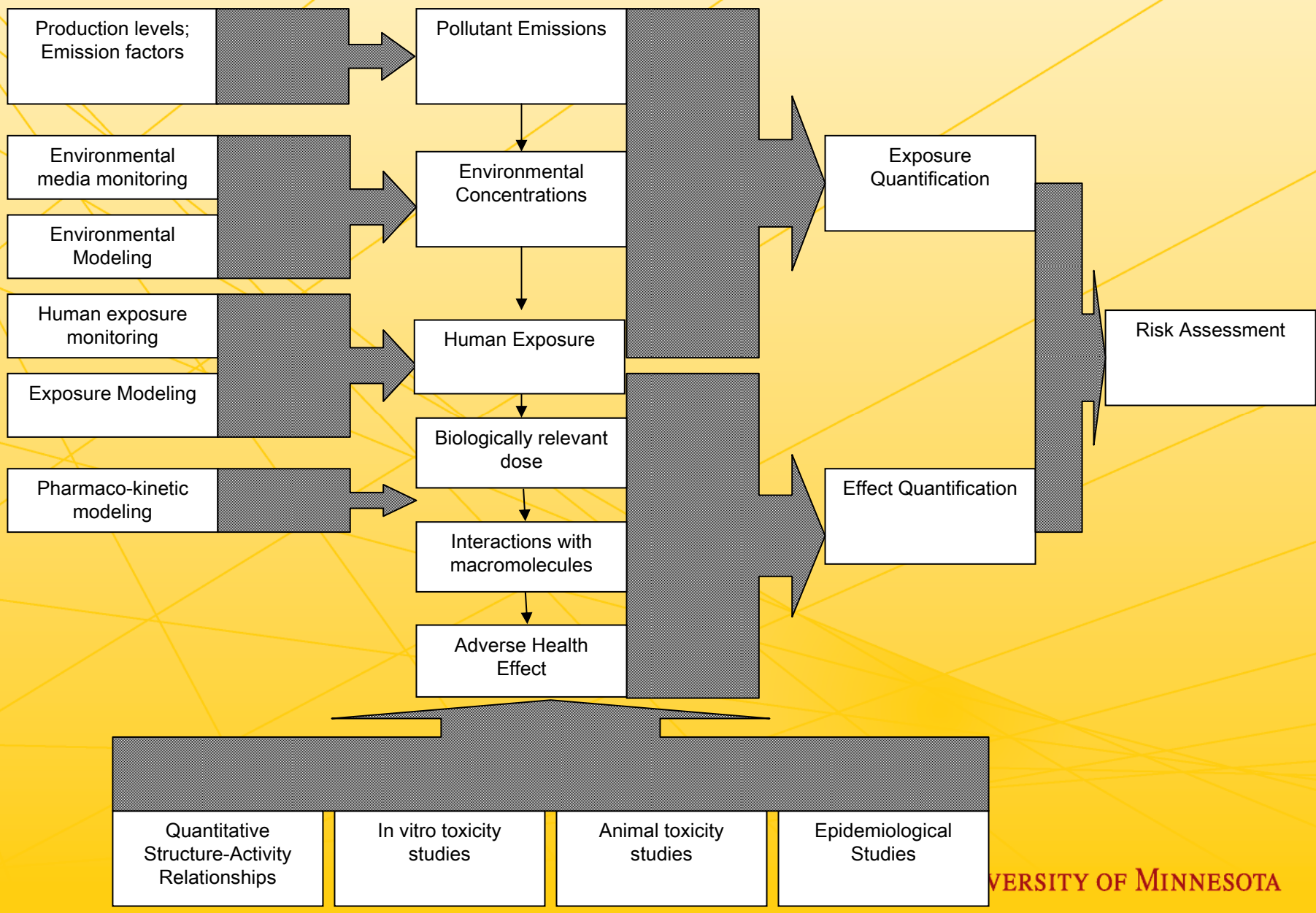
2. Application of oversight lessons to nano-bio-technology (mapping, consensus)

3. Development of oversight models for nanobiotechnology products and research (scenario analysis, consensus)

Risk Perceptions and Analyses-Outline

1. Limitations of current risk assessment paradigm
2. Lessons learnt from oversight of chemicals and chemical RA
3. Implications for nano-bio
4. Risk perception criteria in evaluating oversight models

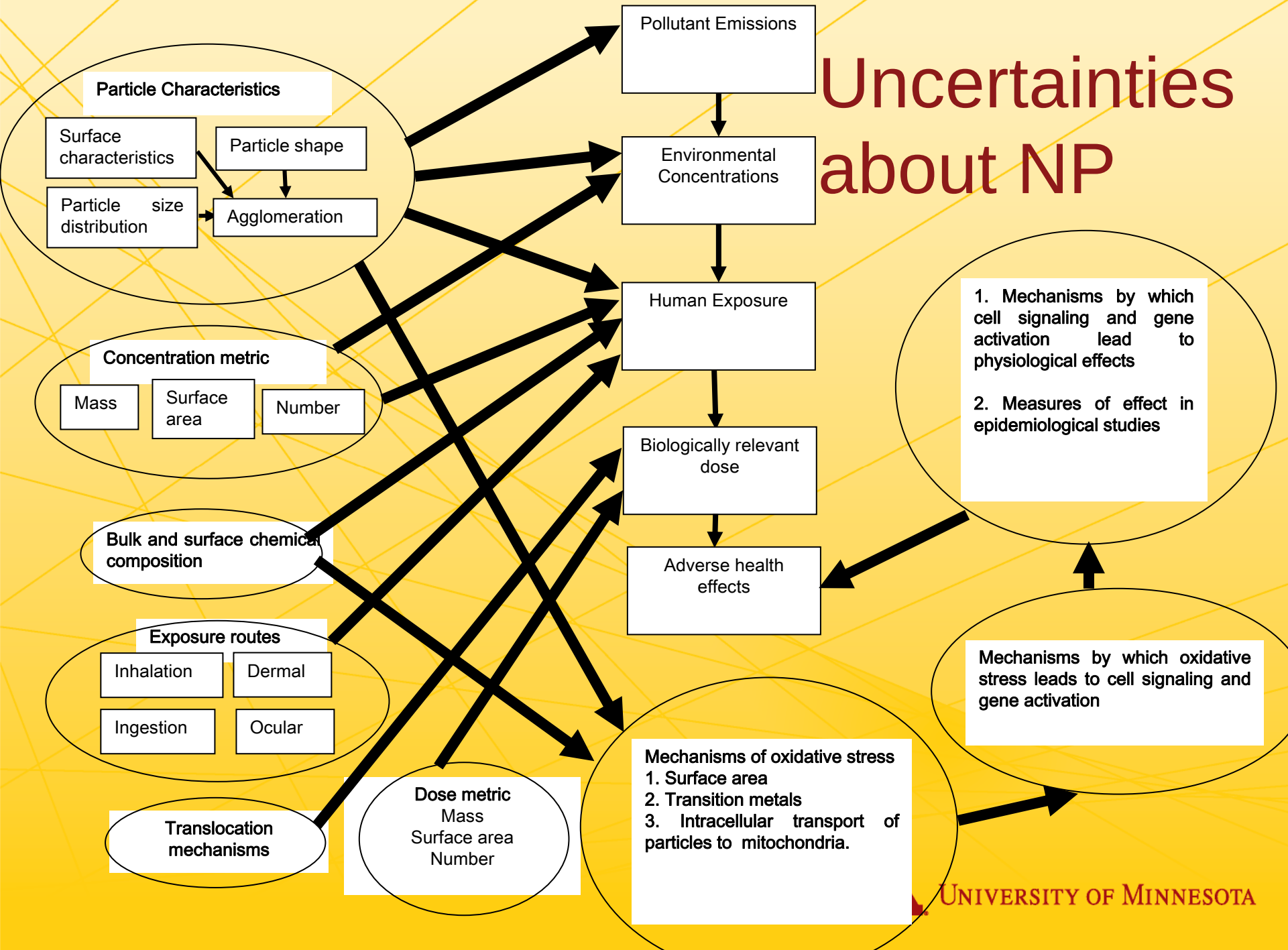
Data needed for classical RA



Limitations of current RA paradigm

- Quantitative risk assessment: basis of considerable amount of policy making
  - Supreme Court (1980) Benzene decision: OSHA must find a significant risk to health (5th Circuit)
  - EPA adopted risk assessment and risk management as agency policy in 1984
- We have adequate information for only a handful of the thousands of chemicals in use.
- Existing regulatory system is incapable of carrying out a detailed RA for every chemical.

Uncertainties about NP



Consequences of Limitations

- Tremendous uncertainties precludes risk assessments using conventional methods.
- Options to Conventional RA:
  - Screening assays
  - Performance-based standards (exposure limits) vs process-based standards (UK)
  - Tiered system of oversight (e.g., REACH in Europe)
  - Expert judgment in RA

Expert Judgments and Risk

- Assessment of probabilities is necessarily subjective (Herman Kahn, 1960)
- **Reactor Safety Study, 1975**
  - Subjective probability assessments show broad spread of values
  - Experts are overconfident
  - They tend to under-estimate risks

Risk Perception

- Risk = *f* (Probability, Consequences)

- Perceived Risk = *f (*Perceived probability, Consequences, Outrage)
- Risk is an emotional concept
- Cannot be separated from psychology

Past Experience with Chemical Risk Assessment

- When faced with great uncertainty in RA, both experts (scientists, regulators, industry) and lay people behave in “predictably irrational ways”. (Kahneman and Tversky, 2000)
  - Exaggeration of small/negligible risks
  - Neglect of real risks
  - Possibility of extreme, unanticipated events

1. How can scientists, regulators and industry manage an unanticipated crisis,?

2. How does the oversight system engender public confidence ?

Risk Perception Related Criteria for Evaluating Oversight Models

A. Development
   i. Impetus
   ii. Public Input
   iii. Empirical basis

B. Attributes
   i. Treatment of uncertainty
   ii. Stakeholder inputs
   iii. Compliance & enforcement
   iv. Considerations of fairness

C. Evolution
   i. Extent of change in Attributes

D. Outcomes
   i. Public Confidence