Life Cycle Approaches to Risk Assessment: Maximizing Benefits

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2009 Summit Environmentally Responsible Development of Nanotechnology
NC Biotechnology Center

Research Triangle Park, NC
October 8, 2009

Maximizing Benefits

- Framing the issues
  - The need to be proactive about impacts
- Life Cycle Assessment
  - Applicability to new technology development
- Risk Assessment
  - Challenges for nanomaterials and nanotechnologies
- Screening Tools

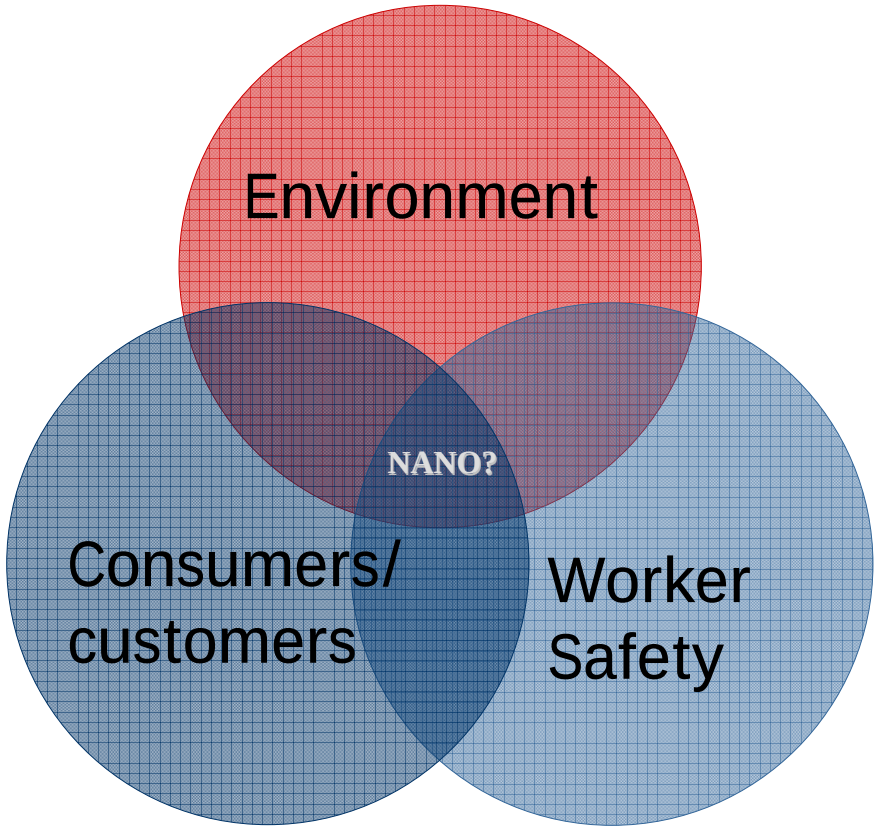
"JUST ANOTHER COUPLE OF PAGES."

Why Be Concerned about Nanomaterial Impacts?

- Novel properties
- History dictates action
- Technology advancing quickly
- Paucity of information
- Potential for wide dispersion in the environment amidst uncertainty
- Significant NGO activity and low consumer knowledge
- Few standards or guidelines - yet!

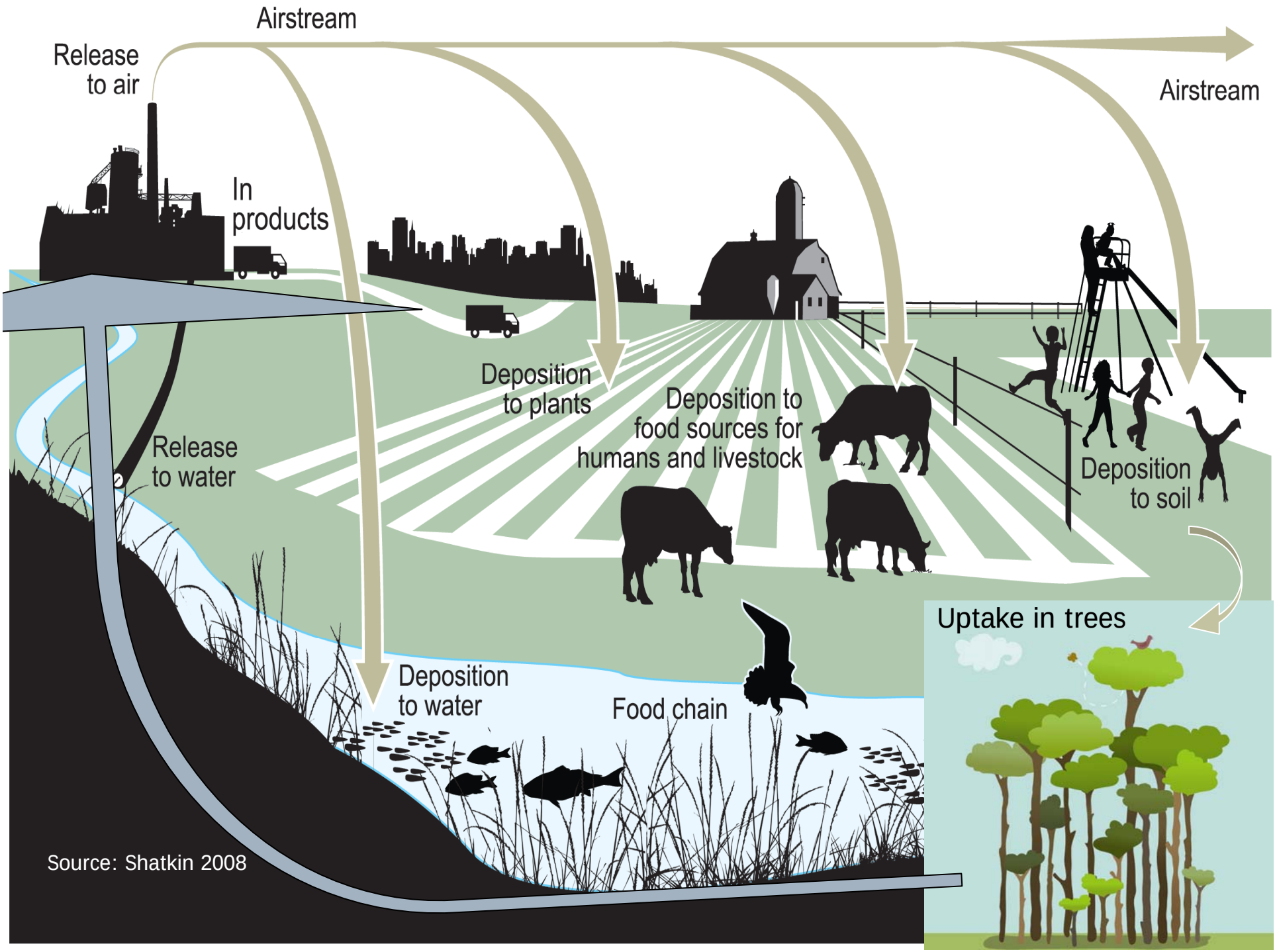
Key Concerns about Nanotechnology Risks

- Avoiding a "nano" legacy
- Uncertainty about health and environmental risks
- Lack of standards
- Hype – its unclear which issues are real, perceptions a risk, too



Promoting Sustainable Technology Development

- Can be proactive about identifying and reducing risk
  - Promotes environmentally sustainable technology development
  - If EHS concerns, need to develop approaches for assessment and management
- Engineering materials provides flexibility to address EHS concerns up-front, if identified
- Understanding impacts provides a competitive edge in efficiently managing them
  - When risks are anticipated, can plan for them, rather than reacting
  - Early stage analysis informs sound decisionmaking


Airstream
Release to air
Airstream
In products
Deposition to plants
Deposition to food sources for humans and livestock
Release to water
Deposition to soil
Uptake in trees
Deposition to water
Food chain
Source: Shatkin 2008

Life Cycle Assessment

A compilation and evaluation of the inputs and outputs and the potential environmental impacts of a product system through its life cycle (ISO 14040)

The main steps in an LCA

- INVENTORY
  - Describe emissions and raw materials used during the life of a product
- IMPACT ASSESSMENT
  - Assess the impacts of these emissions and raw material depletions on
    - Greenhouse effect (or potential global warming)
    - Ozone depletion
    - Acidification
    - Eutrophication
    - Summer Smog
    - Natural resource depletion
    - Aquatic toxicity
    - Human Health
- INTERPRETATION

Woodrow Wilson International Center for Scholars

Project on Emerging Nanotechnologies
at the Woodrow Wilson International Center for Scholars

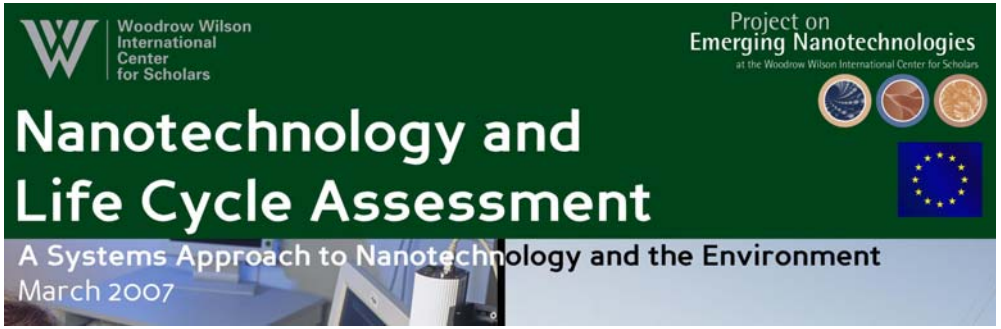
Nanotechnology and Life Cycle Assessment

A Systems Approach to Nanotechnology and the Environment

March 2007

Synthesis of Results obtained
at a workshop in Washington, D.C., 2-3 October 2006

Select Conclusions



- The ISO-framework for LCA (ISO 14040:2006) is fully suitable to nanomaterials and nanoproducts, even if data regarding the elementary flows and impacts might be uncertain and scarce.
- While the ISO 14040 framework is appropriate, a number of operational issues need to be addressed in more detail in the case of nanomaterials and nanoproducts. **The main problem with LCA of nanomaterials and nanoproducts is the lack of data and understanding in certain areas.**
- While LCA brings major benefits and useful information, there are certain limits to its application and use, in particular with respect to the assessment of toxicity impacts and of large-scale impacts.
- Within future research, major efforts are needed to fully assess potential risks and environmental impacts of nanoproducts and materials (not just those related to LCA).

Risk Assessment

A process intended to calculate or estimate the risk to a given target organism, system or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. (WHO. 2001)

Understanding risks allows efficient management of them

- Risk Assessment:
  - Is increasingly part of regulatory structures
  - Allows decision making under uncertainty
  - Can address potential concerns throughout the life cycle of a product
  - Prioritizes research directions
  - Identifies areas for product innovation
  - Reduces potential for unforeseen impacts
  - Provides a tool box of approaches

Advantages of a Risk-based Approach

- Practical
  - Can inform decision making
- Efficient
  - Early screen for liabilities, required testing
- Proactive
  - Considers technical, societal, market and regulatory

Differentiating Hazards from Risks

- All materials are toxic at some concentration
- Risk = hazard * exposure probability
- There must be an exposure for there to be a risk

Society for Risk Analysis

27 year old professional society

2000 member international organization

Interdisciplinary – breadth of expertise in risk specialty groups for disciplines

In December 2006 formed the Emerging Nanoscale Materials Specialty Group (EMNMS) with 75 founding members.

Risk Analysis:

Advancing the Science for Nanomaterial Risk Management Sept 2008, Washington DC

- Public expert workshop organized by the Society for Risk Analysis *Emerging Nanoscale Materials Specialty Group*
- Brought together risk analysts with nano-experts in to advance our understanding and build new networks
- A deliberative workshop to address:
  - What is "nano" about risk assessment for nanoscale materials?
  - What tools in the field of risk analysis can be used for managing nanomaterials?
  - What are the needs for communicating about risks?
  - How to consider the benefits of nanotechnology for risk reduction?

Workshop Co-Sponsors


start

Key Issues Identified

- Many previously identified concerns are not specific to nanomaterials or nanotechnologies
- Can address some concerns "by design"
  - Engage risk analysts to work with product designers
- Need for a long term plan/framework to answer questions with pending data
- Conduct case-by-case evaluations to elicit key concerns
- Also conduct expert workshops more broadly to raise overarching issues
- Test/compare adaptive approaches to risk analysis that incorporate the product life cycle

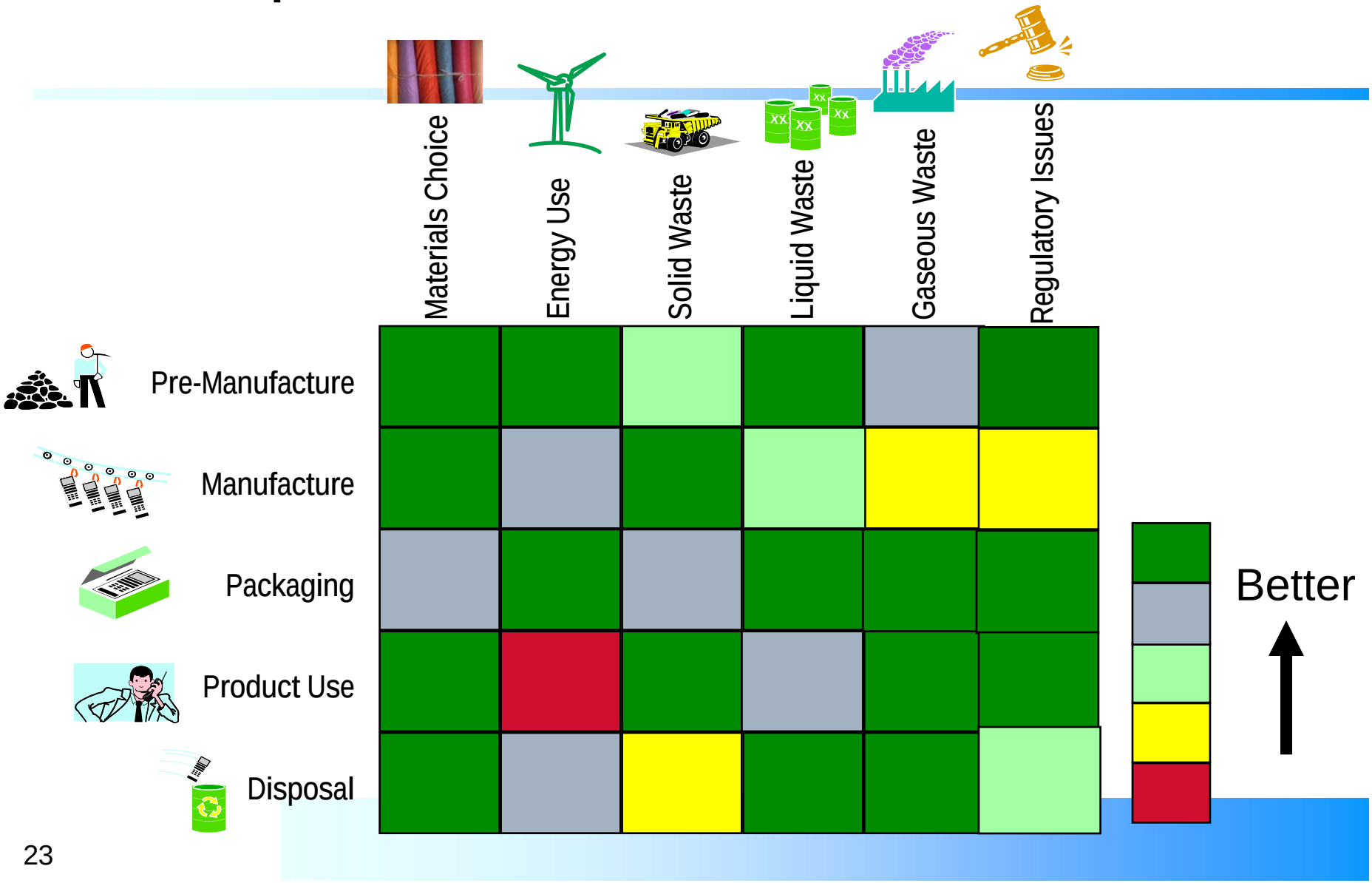
Framing the Issues: Characterizing Risks of Nanomaterials

- Several deliberations conclude that current frameworks adequate and appropriate
  - but significant model and parameter uncertainty
- Still much research to be done to quantify risks
- Need to address uncertainty and variability
- Still a limited ability to conduct quantitative assessments
- New metrics and endpoints for risk?

Streamlined Life Cycle Risk Assessment

- Helpful for identifying “hot spots” and highlighting key opportunities for instituting environmental improvements
- Can quickly and accurately identify the environmental impacts of a product or service over its entire lifecycle
- Highlights system inefficiencies, areas of previously-unseen risk as well as promising opportunities for financial reward

Sample SLCRA Matrix



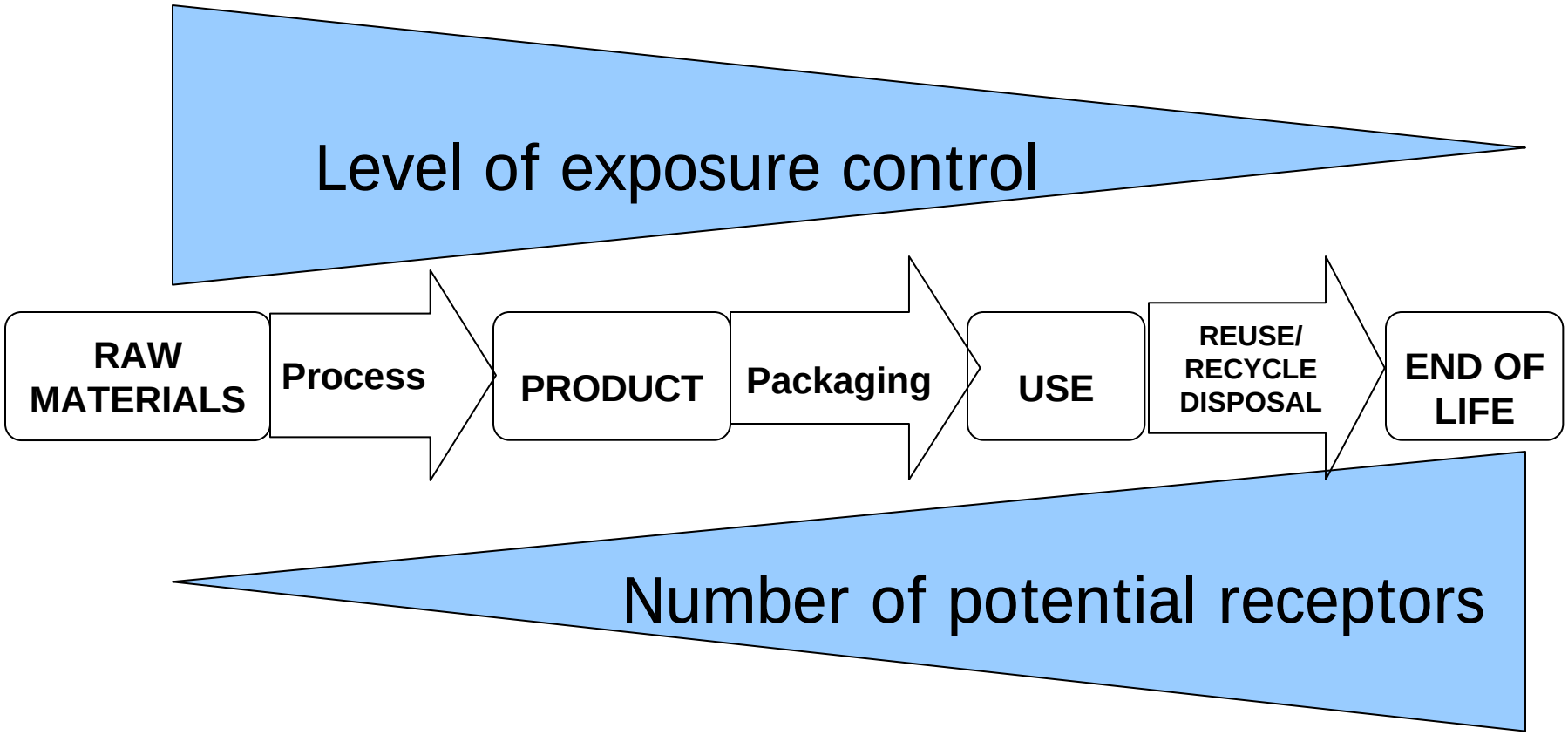
Key Elements of a Risk-based Analysis Framework for Nanomaterials

- Tiered – Start with Screening Tools
  - Use early in the product development cycle to identify potential concerns
- Address Life Cycle Concerns
  - Consider worker, consumer, and environmental issues
- Focus on Exposure
  - Indicators, not Perfect Data
  - Hazard, Exposure and Toxicity Dimensions
- Adapt Products to Findings (Evaluative)
  - Incorporate findings into actions

Screening for Potential NANO Risks across the Product Life Cycle

- Raw materials
  - novel structures, material combinations, ↑ reactivity
- Manufactured Products
  - New potential exposures, applications, waste generation
- Packaging and distribution
  - Customer knowledge, communication, labeling
- Product Usage
  - Novel behavior in matrix, potential consumer exposure
- End of Life
  - Environmental dispersion; recycling/disposal impacts

In the product life cycle, environmental exposures are less easily assessed and managed



Proposed Life Cycle/ Risk Frameworks for Nano

- Life Cycle Approaches to risk incorporate biological and environmental exposures in the framework
  - **Nano SLCRA** (Shatkin 2008. *Nanotechnology Health and Environmental Risks* CRC Press)
  - **CEA** Comprehensive Environmental Assessment (Davis 2007)
- Screening Approaches can still be data intensive
  - **Nano Risk Framework** (EDF/DuPont 2007)
  - **ILSI RF Risk Screening Framework** (toxicology only)

International Life Sciences Institute – Risk Sciences Institute Screening Approach

Physical Chemical Properties

- *particle size and size distribution*;
- *shape*;
- *surface area*;
- *chemical composition*;
- *surface chemistry*;
- surface contamination;
- *surface charge (in suspension, solution, and in powder form)*;
- *crystal structure*;
- particle physicochemical structure;
- *agglomeration state*;
- *porosity*;
- method of production;
- preparation process;
- heterogeneity;
- prior storage of material; and
- concentration

***In vitro* assays**

Cellular

- lung;
- skin;
- mucosal membrane;
- endothelium, blood;
- spleen;
- liver;
- nervous system;
- heart; and
- kidney studies.

Non-cellular

- nanoparticle durability;
- protein interactions;
- complement activation;
- pro-oxidant activity.

***In vivo* assays**

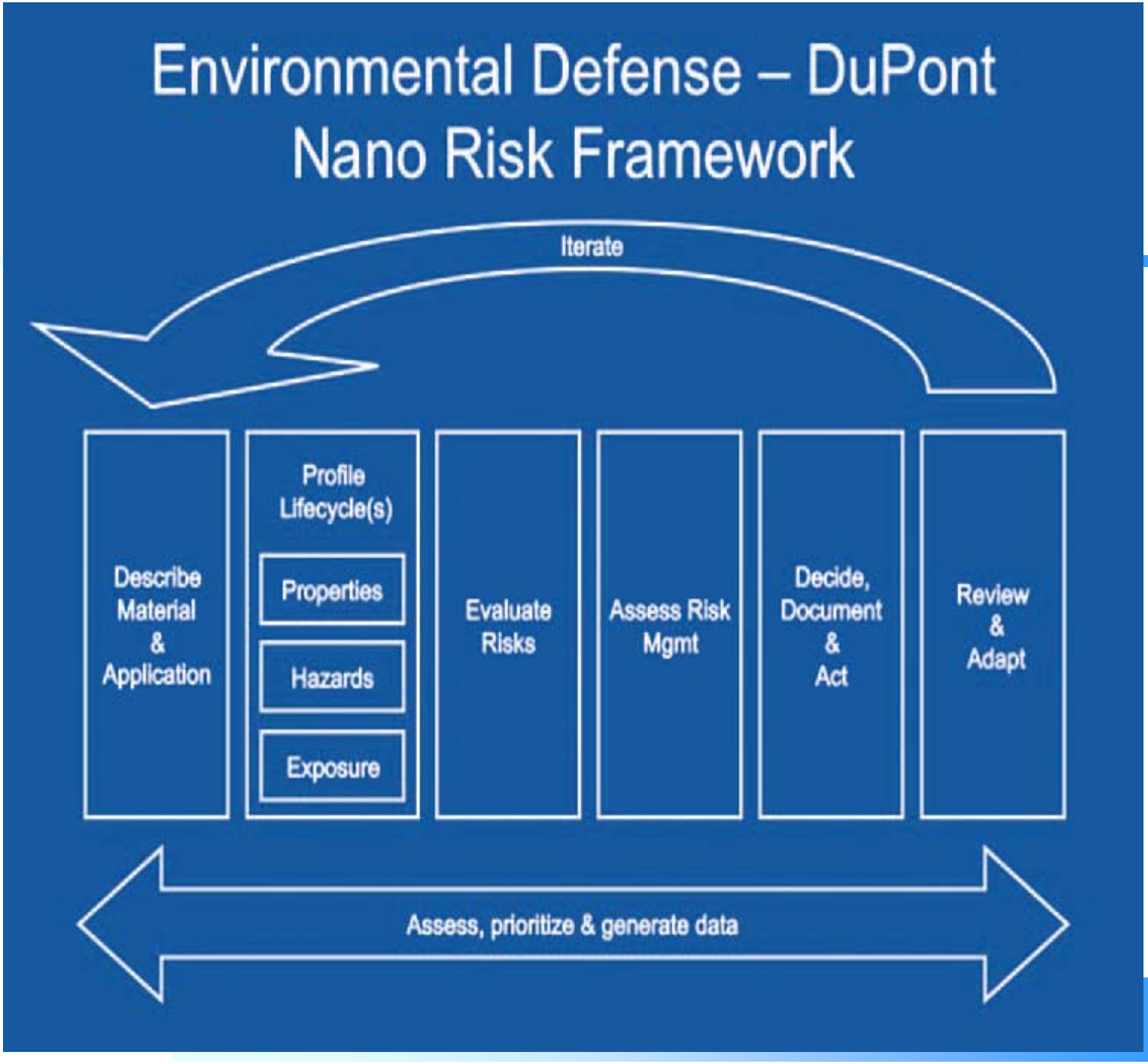
Tier 1 evaluations for

- pulmonary, oral, dermal and injection exposures;
- inflammation;
- oxidant stress; and
- cell proliferation in select organs.

Tier 2 evaluations for

- pulmonary exposure;
- deposition; translocation;
- toxicokinetics/biopersistence studies;
- multiple exposure effects;
- reproductive effects;
- alternative model studies;
- mechanistic studies

Oberdöerster, G. et al. 2005. *Particle and Fibre Toxicology* 2005, **2**:8
http://www.particleandfibretoxicology.com/content/2/1/8


Environmental Defense – DuPont
Nano Risk Framework
Iterate
Describe Material & Application
Profile Lifecycle(s)
Properties
Hazards
Exposure
Evaluate Risks
Assess Risk Mgmt
Decide, Document & Act
Review & Adapt
Assess, prioritize & generate data

Comprehensive Environmental Assessment (CEA)

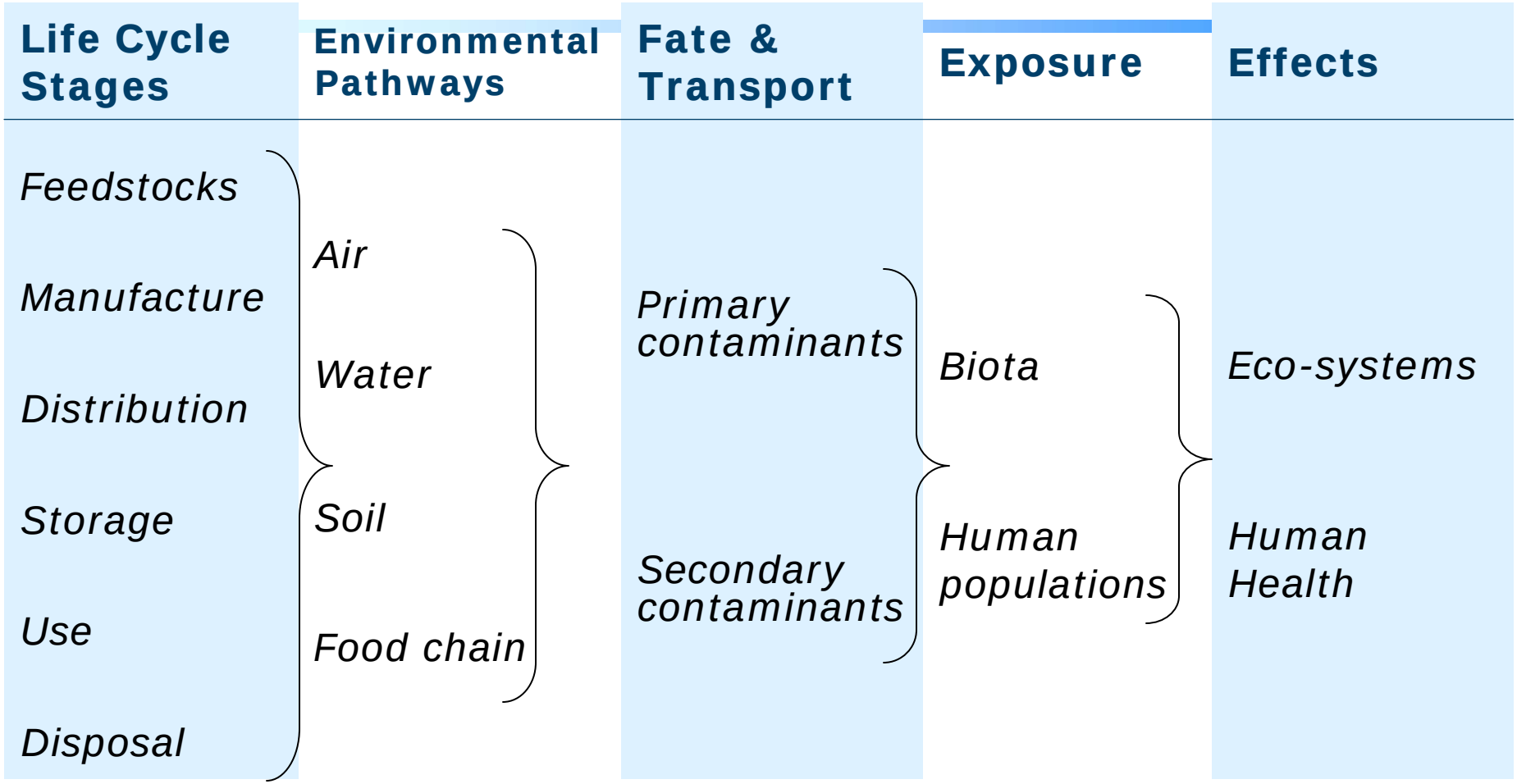
$$CEA \approx LC + RA$$

LC = Product Life Cycle framework

RA = Risk Assessment paradigm

See: Davis, J. M. "How to assess the risks of nanotechnology: learning from past experience" *J. Nanosci. Nanotechnol.* 7(2): 402-409, 2007

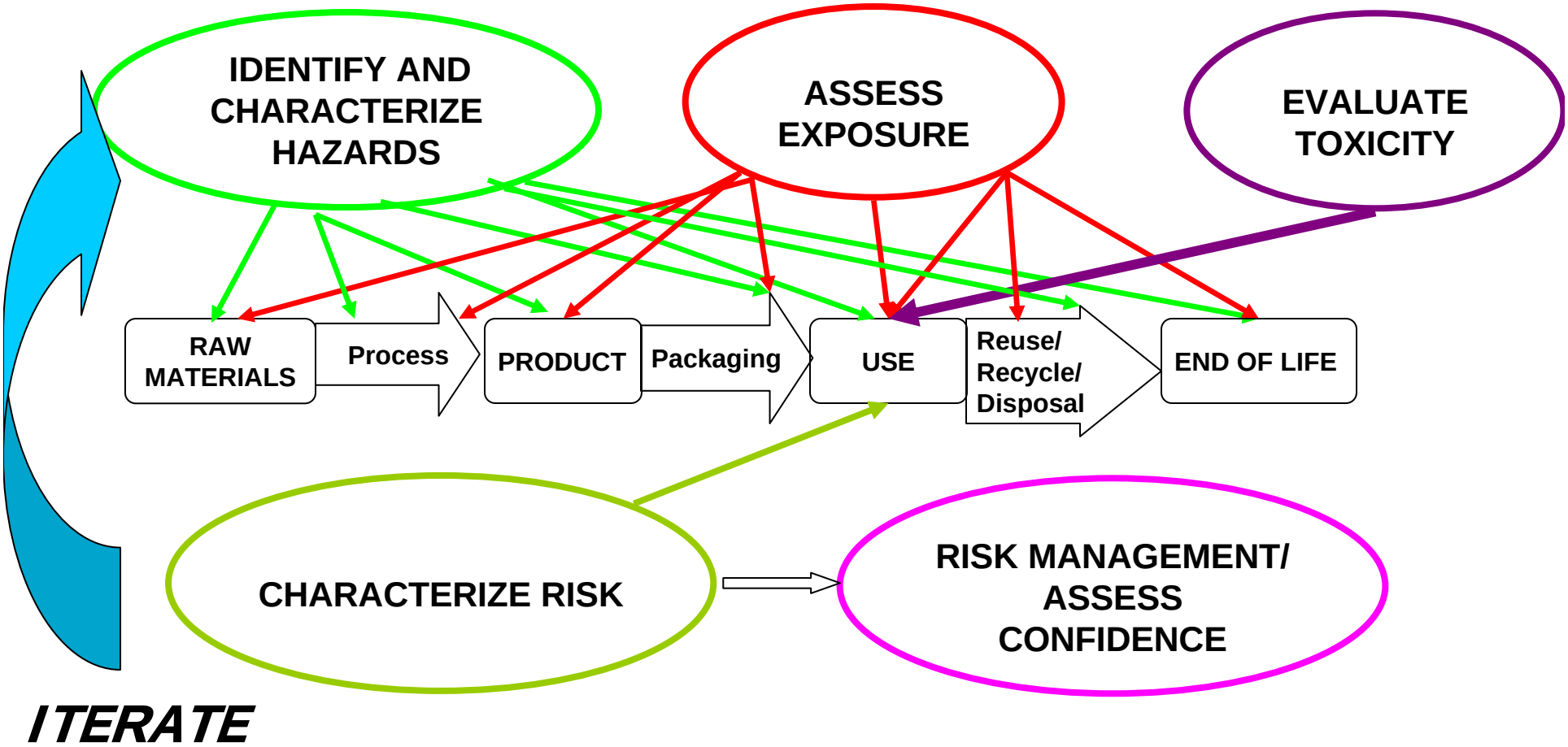
Comprehensive Environmental Assessment (CEA)



Source: adapted from Davis, J. M. and Thomas, V.M. *Annals N.Y. Academy of Science* 1076: 498-515, 2006

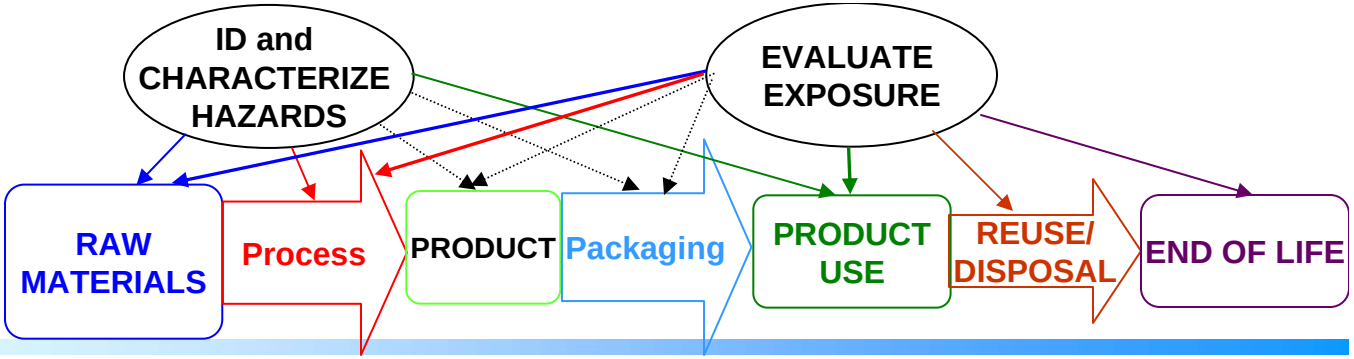
NANO SLCRA

Adaptive Streamlined Life Cycle/ Risk Assessment Framework for Nano Materials (Shatkin 2008)



NANO SLCRA

Case Example Nanocrystalline Cellulose for Packaging Application



Analysis

Hazard Identification

- No nanomaterials in raw materials
- Extract released during isolation process
- Uncontained disposal practices for Nano-containing wastes
- Product contains unbound crystalline particles
- Post application recycling distributes nanoparticles

- ***Exposure Assessment***

- Material production process not enclosed
- Packaging process is very dusty
- Use exposes consumers to nanoparticles
- Disposal practices create secondary human exposure pathways

Recommendations

Toxicity Assessment

- Material characterization
- Design protocol to assess toxicity of packaging product in vivo and in vitro

Inhalation and Dermal Exposures

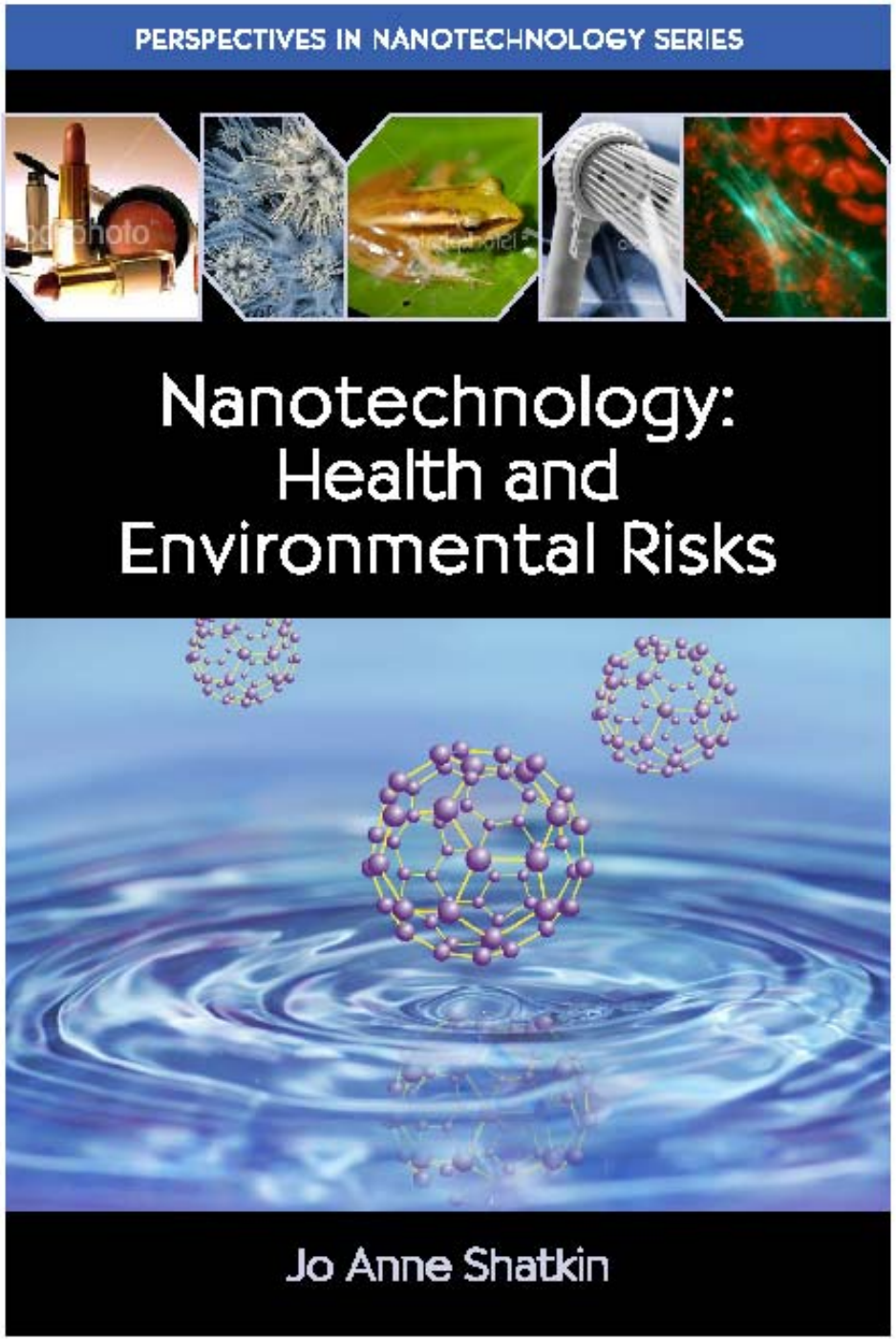
- Develop tracking system
- Work with solutions not particles
- Contain process releases
- Provide PPE/training for handling production materials
- Conduct training
- Develop MSDS
- Assess use/disposal exposures

NANO SLCRA Streamlined Framework

- Use as a screening tool to identify and prioritize health and environmental/ process issues
- Complement with regulatory/ market competition/ societal concern analysis
- Analysis identifies key uncertainties – can inform product development
- Revisits early decisions with new information

NANO SLCRA Features

- Proactive, early stage, affordable, easily implementable process even with few available data.
- Develops risk management practices based on minimizing exposure and potential human health effects and environmental impacts.
- Applicable for NM research and development, product manufacturing, consumer applications, and evaluation of NM fate in the environment.
- Prioritizes future data needs.


PERSPECTIVES IN NANOTECHNOLOGY SERIES
Nanotechnology:
Health and
Environmental Risks
Jo Anne Shatkin

Summary

- Innovation is inherently risky
- The environmental, safety and health aspects of innovative materials are not well understood and are perceived as risky
- Companies, workers, customers and the environment benefit from a proactive approach to identify and address potential risks early in the innovation cycle
- Screening Level Risk Assessment is a useful tool for identifying and managing amidst uncertainty

"Look, I'd like to avoid overkill, but not at the risk of underkill."

Source: K. Thompson, 2004.

Thank You Very Much!

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