A RISK ASSESSMENT FRAMEWORK TO GUIDE DEVELOPMENT OF EMERGING NANOSCALE FOREST PRODUCTS

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Emerging Nanotechnology Industry

- Hundreds of products already in the market
- Expanding gap between product development and regulatory capacity
- Incongruity
  - Projections of major influx of new products
  - “Assurances” that there will never be enough material to reach substantive exposure concentrations to harm humans or ecological resources
- Forest Products
  - Nano-composites
  - Novel wood preservatives
  - Upgrading pulp waste streams to yield value-added chemicals
  - Flexible coatings as protective barriers
  - ...
- Contemplated environmental uses
  - Remediation technology
  - Antimicrobials to treat bio-fouling
- Large quantities of waste by-products
European Forest Product Focus


... the scientific base for the transition of European production industry from a resource-based towards a knowledge-based [economic power], [with a] more environment-friendly approach.

- Encompassing nano-technologies and long-term interdisciplinary research extending to new materials and engineering techniques,
- renewable biomaterials,
- use of natural raw materials

- Lists 44 active research projects: safer solvents, wood treatment, stronger materials, novel products, higher percentage of use of raw material, ...

- Aggressive development
  - Strength of the forest products industry in Nordic countries
  - Strength of the European chemical industry
  - Close and symbiotic relation between the European forest industry and chemical industry clusters is being promoted
EFFECTIVENESS OF A RISK ASSESSMENT FRAMEWORK TO INFORM PUBLIC PERCEPTION

Theoreticians

Applied Scientists

Engineers

Anticipatory

Crisis

BEST OPPORTUNITY TO SAVE RESOURCES, COST, REDUCE RISK AND NEGATIVE PUBLIC PERCEPTION

Dissemination of Information
- Often erroneous
- Often incomplete
- May generate negative public perception
- May create “crisis” mentality

Triggering Event
(e.g. accidental release raising fears of mortality/morbidity to receptors)

Resolve Conflicts
Gain Publics’ Confidence

Lose Publics’ Confidence

CURRENT STATE OF NANOTECHNOLOGY RESEARCH AND DEVELOPMENT

Funding Sources:
- Academic Institutions
- Entrepreneurs
- Economic Development Programs

Interest Groups:
- Regulatory Agencies
- Environmental Groups
- Technology Companies

Politicians

Triggers Event

Media

General Public/Activist Groups

Business Developers

Marketers

Sales

Risk Assessment

- Examines scenarios
  - Estimates magnitude of exposures
  - Relates exposures to effects
- Evaluates the likelihood of an event occurring

Stakeholders, including the nanotechnology industry, will benefit from an integrated decision framework that considers socioeconomic, human health, and ecological risk with a product “Life-Cycle Analyses” perspective.
Risk Assessments Foster Informed Decision-making

**Scoping**
- Problem Formulation
- Analysis
- Risk Characterization

**Screening**
- Problem Formulation
- Analysis
- Risk Characterization

**Definitive**
- Problem Formulation
- Analysis
- Risk Characterization

Decision

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http://pubs.acs.org/subscribe/journals/esthag/40/i14/html/071506feature_wiesner.html
Mean (±SEM) number of cocoons of 5 adult worms following 28 days of exposure to food contaminated with double-walled nanotubes (DWNT).

EC10 = 37±73 mg/kg DWNT
EC50 = 176±150 mg/kg DWNT

### Classifying, Communicating, and Managing Risk

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<th>Likelihood</th>
<th>Environmental Consequence</th>
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<tr>
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<td>Very Unlikely</td>
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- **I** = Inherent Risk
- **R** = Residual Risk
- **T** = Technology
- **M** = Management
Stages of Assessment for Nanotechnology

- Conceptual Beginning
  - QSAR-like classification Guiding
    - Pre-feasibility
    - Worker Safety
- Bench-scale Testing
  - Generic Testing
    - Environmental fate
    - Inherent toxicity
- Pilot Production
  - Expanded Safety Testing in relevant media
    - Human receptors [surrogates]
    - Ecological receptors [direct or surrogates]
  - Preliminary Risk Assessment for generalized scenarios
- Commercialization
  - Detailed Integrated Risk Assessment
  - Considers specific scenarios relevant to both intended and unintended uses
- Post-commercialization
  - Risk-based monitoring to validate assumptions
  - Active Adaptive Management to address realized risks

Contemporary Activities

- **Professional Societies**
  - SRA organized a Section on Nanotechnology at its annual North American meeting in 2006
  - SETAC formed working group in 2007 that is examining five topical areas
    - 1) terminology, 2) environmental fate and behaviour, 3) toxicokinetics and bioconcentration, 4) ecotoxicology, 5) risk assessment framework

- **Government Bodies**
  - US EPA, Environment Canada and Health Canada, and the European Community have launched exploratory studies of NPS. Some municipalities have considered policies pertaining to the nanotechnology industry
  - Economic Development programs

- **Industry**
  - Environmental Defence—DuPont Partnership
  - CEFIC Long-range Research Initiatives

- **ASTM-I, OECD, ISO have initiated work to develop standards for testing and handling NPs**
  - ASTM-I is examining the full suite of toxicity test methods to determine adequacy for addressing NPs
  - Emphasis on special characterization steps required to document exposure regimes
  - Other considerations
    - test volumes
    - relevant endpoints,
    - interpretation of effects data