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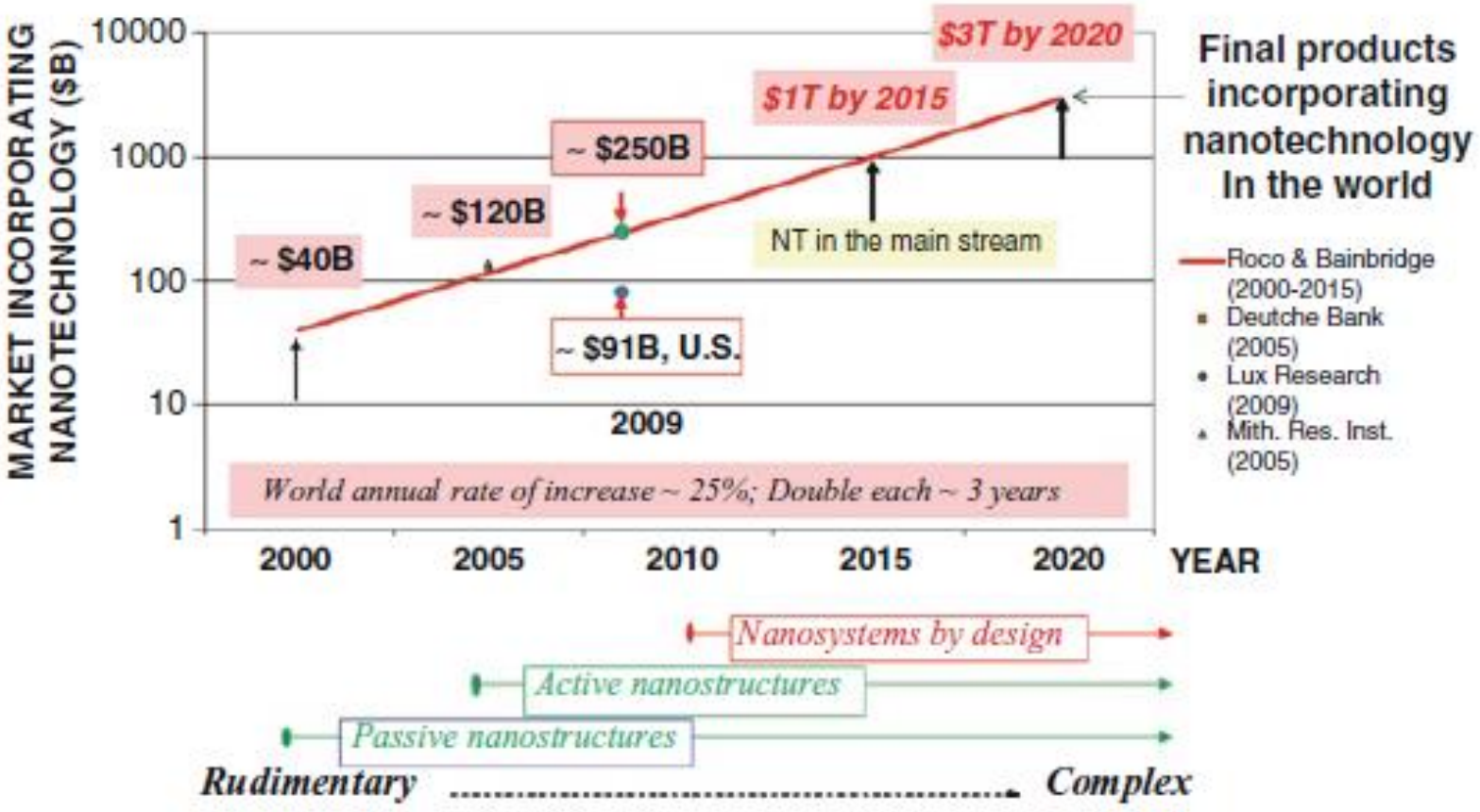
Product Stewardship for Nanotechnology Products: Current Regulations and Beyond

Linda Dell, MS

ENVIRON

Market trends



Source: Roco, Mihail C. "The long view of nanotechnology development: the National Nanotechnology Initiative at 10 years." Nanotechnology Research Directions for Societal Needs in 2020. Springer, 2011. 1-28.

What is product stewardship?

Stewardship:

> The activity or job of protecting and being responsible for something…

Merriam-Webster

Benefits of Product Stewardship

Access to commercial markets

Regulatory Compliance

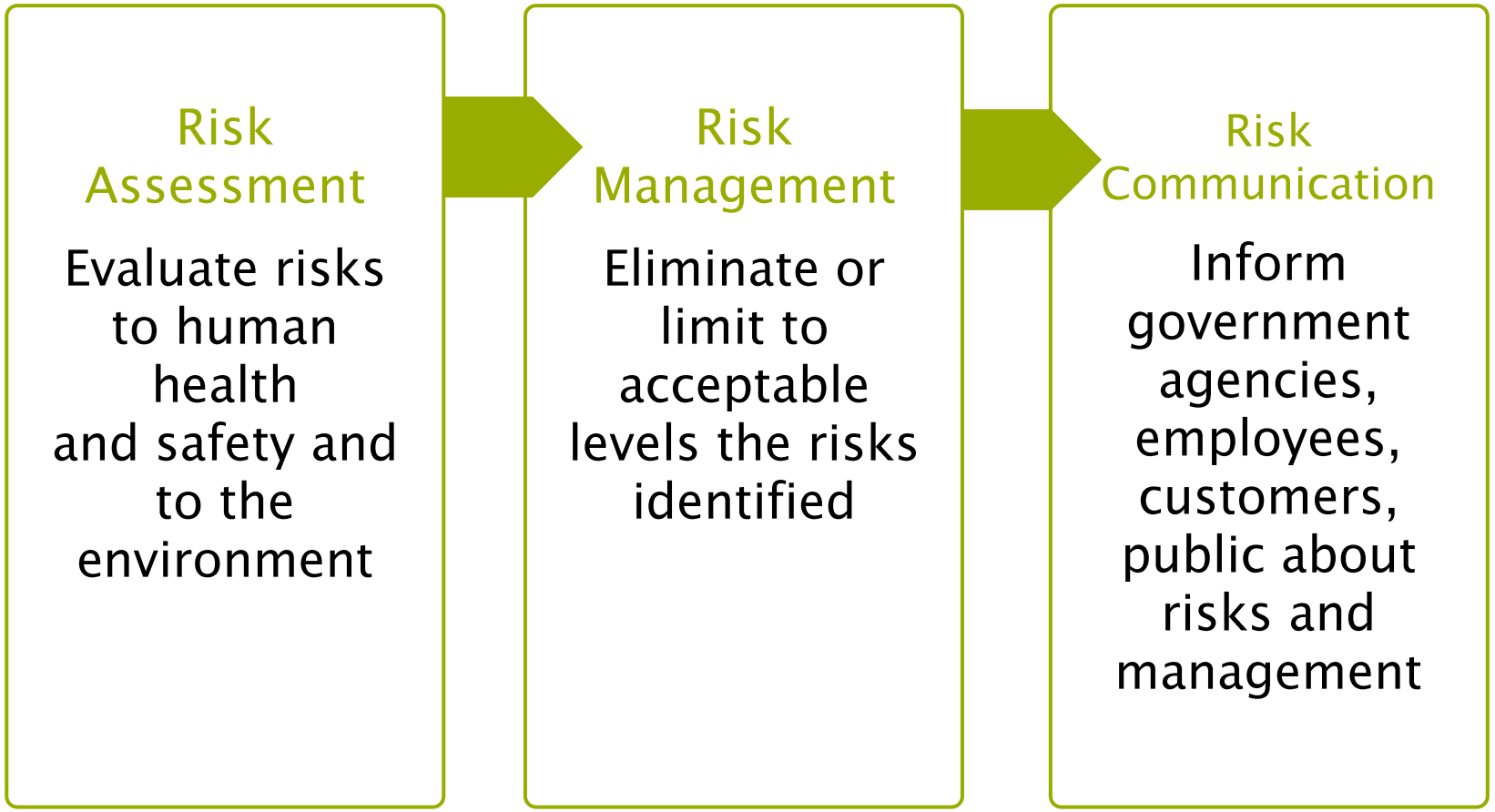
Optimize market opportunities

Increase reputation

Minimize business risks and liabilities

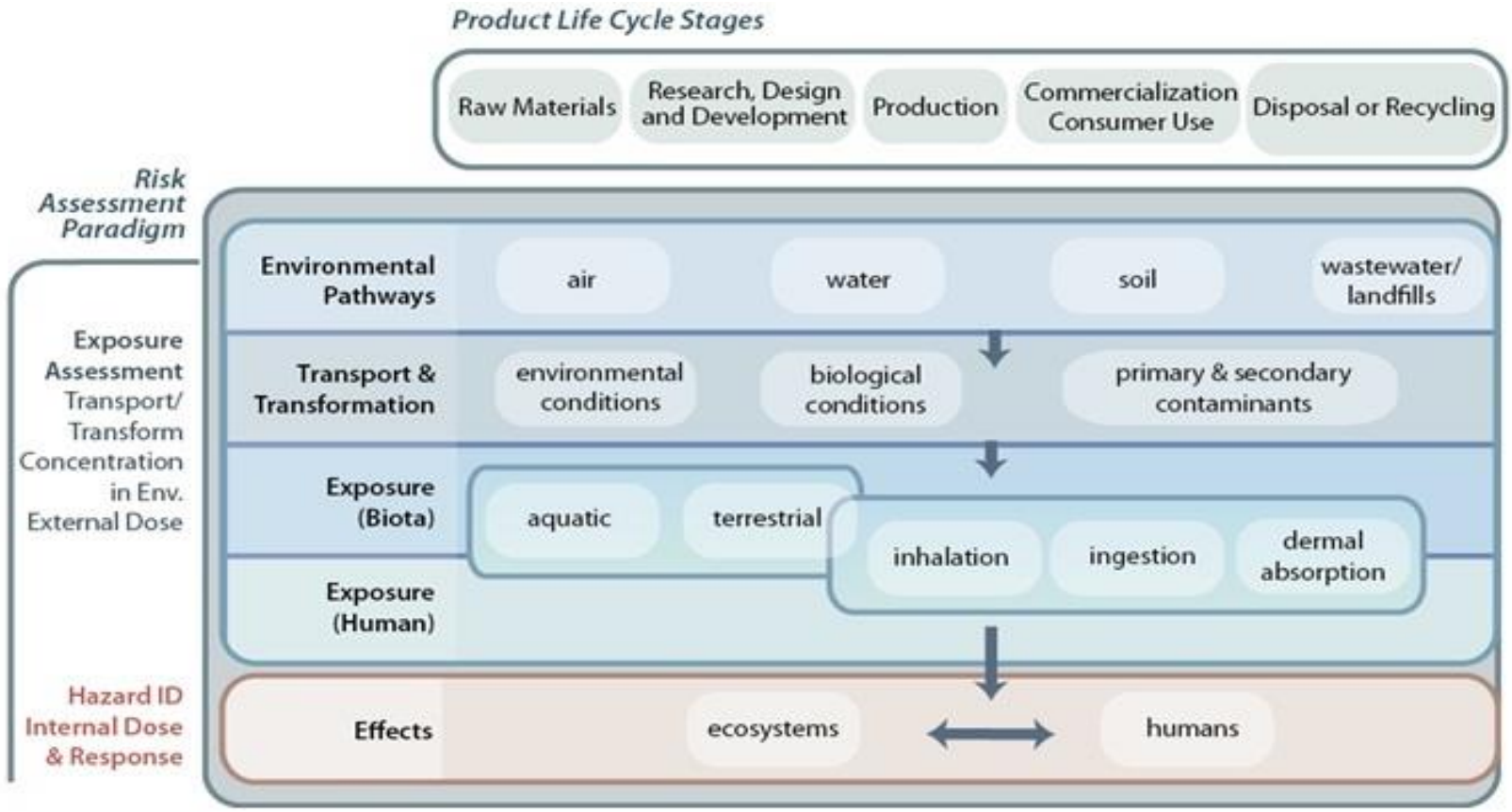
Product Stewardship

Components of a Proactive Product Stewardship Program



Source: Rodricks JV. Risk Analysis and Product Stewardship: A Guide for Manufacturers. ENVIRON International, Arlington, VA.

Life Cycle Assessment



Source: National Nanotechnology Initiative (www.nano.gov)

Regulation of Nanomaterials

Unresolved Issues?

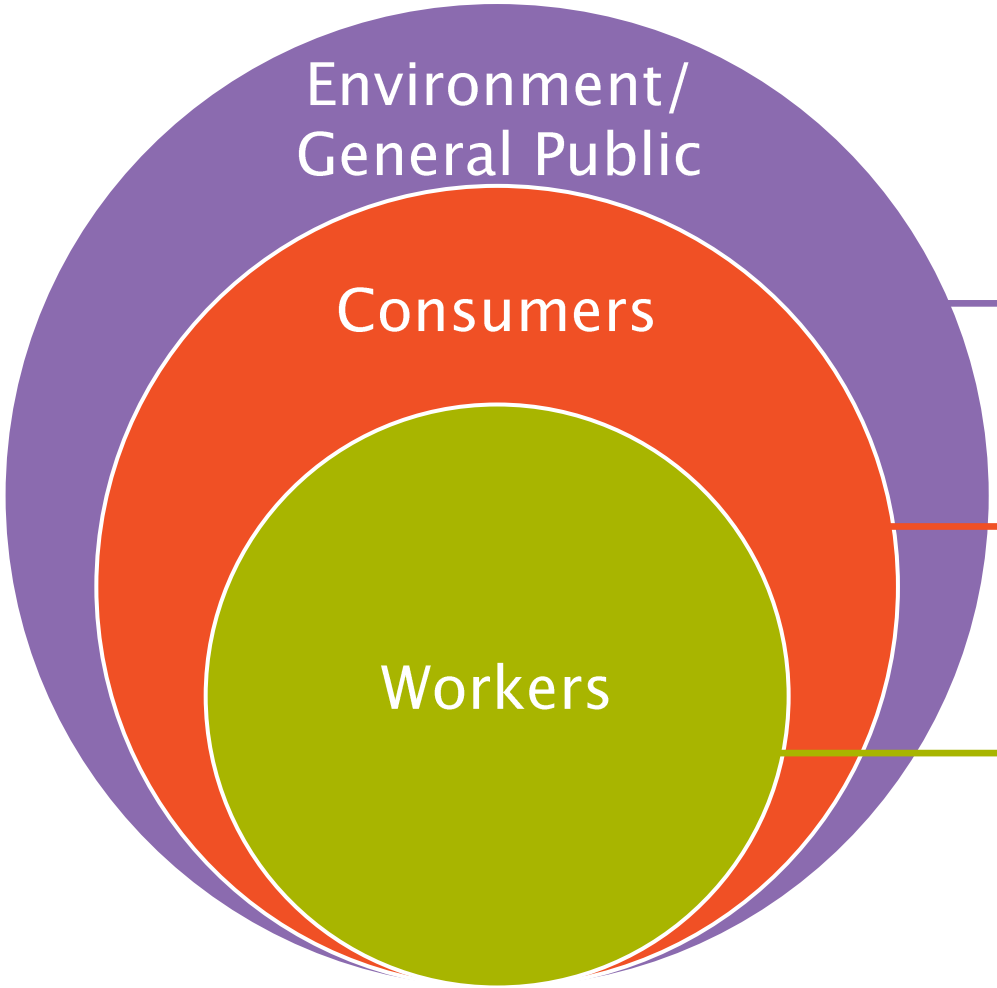
- Definitions of nanomaterials
- Risk characterization
- Different regulatory standards/frameworks
- Responsibility for regulation, authorization, and enforcement
- Enacting rational and reasonable regulations

Regulation of Nanomaterials

Definitions

- Natural, incidental or manufactured
- Nanoscale (1 – 100 nm)
  - One or more external dimensions, OR
  - Has internal or surface structure at nanoscale ("nanostructures") to include primary particles that form aggregates and agglomerates
- Containing ≥10% [≥50%] particles < 100 nm
- Other criteria
  - Novel properties and functions due to nanosize
  - include sizes < 1 nm

Risk characterization and regulations



- EPA, releases, disposal, re-use (little or no data available)
- CPSC, FDA, EPA
- Direct and indirect exposures
- OSHA, EPA
- OELs, measurement of exposure, hazard classification and communication

Regulation of Nanomaterials

Sufficient data to characterize risks?

- Small stuff has unique properties and behaves differently from bulk forms; hazards may be different
- Hazard characterization: requires different testing protocols
  - OECD work programs
  - Challenges: physical chemical properties, hazards identification
- Exposure characterization
  - inhaled mass, number, surface area, surface reactivity, etc.
  - No agreed methods or tools to describe such multidimensional exposure profiles.
- Exposures and risks need to be characterized across workers, consumers, and the environment

Differences in Regulatory Frameworks

UNITED STATES

TSCA (1976)

Assure that chemicals in commerce do not present an "unreasonable risk of injury to health or the environment"

CANADA

CEPA (1999)

9 Guiding Principles including:

Virtual elimination of PBT chemicals

Pollution Prevention

Precautionary Principle

Ecosystems Approach

Sustainable Development

EUROPE

REACH (2007)

Protect human health and environment

Move to alternatives for certain hazardous chemicals

Avoid animal testing

Promote free movement of chemicals on EU market

Differences in Regulatory Frameworks

UNITED STATES

TSCA (1976)

Burden is on regulators to demonstrate adverse effects of chemicals in commerce

Existing chemicals: No requirement to prioritize and assess

New Chemicals: Submit existing data with Premanufacture Notice (PMN)

CANADA

CEPA (1999)

Burden is on regulators to prioritize chemicals

Existing chemicals: Categorization and review of existing chemicals is required

New Chemicals: Notification required

EUROPE

REACH (2007)

Burden is on industry to demonstrate chemicals are safe to use

"No Data, No Market"

Data required for quantities M/I > 1 tonne

US EPA: Existing Instruments for Regulating Nanoscale Substances

Toxic Substances Control Act

- Significant New Use Rules (SNURs)
- Under section 5(a)(2), EPA would require persons who intend to manufacture, import, or process new nanoscale materials based on chemical substances listed on the TSCA Inventory to submit a Significant New Use Notice to EPA at least 90 days before commencing that activity (existing SNURS for CNT and CNF)
- Information Gathering
- Under section 8(a), EPA is developing a proposal to establish reporting requirements for certain nanoscale materials.
- Testing
- Under section 4, EPA would require manufacturers to study adverse health effects of multi-walled carbon nanotubes and nanoscale clays and alumina.

US EPA: Existing Instruments for Regulating Nanoscale Substances

Federal Insecticide, Fungicide and Rodenticide Act

- The presence of a nanoscale material in a pesticide product is reportable under section 6(a)(2).
- Applies to already registered products as well as products pending registration.
  - An active or inert ingredient would be considered “new” if it is a nanoscale material.
  - e.g.: Nanosilver would be considered new even though silver is a registered pesticide.

Europe: REACH

Update and Status

- Registration
  - 10,203 substances have been registered as of September 2013
    - 4 nanoforms; some bulk materials that have nanostructures
- Evaluation
  - CoRAP: 152 substances for evaluation by member states 2012-2015
    - 2 substance characterization/nanoparticles/toxicity of different forms
  - Dossier Evaluation – ongoing
- Authorization
  - Approximately 156 substances (or substance groups) are on the Candidate List
  - 24 substances are subject to Authorization
- Restriction of Chemicals
  - 63 entries affecting 105 substances subject to market restrictions

ECHA: Existing Tools for Regulation of Nanoscale Substances

REACH

- Article 36 decisions
  - Requires registrants to provide available information (not new testing);
    - Examples: technical specifications such as size grades or surface treatment placed on the market; nano-by- design
- Evaluation processes
  - Compliance Checks / Dossier Evaluation
    - Generate new information, physical chemical properties, hazards, exposure
  - Substance Evaluation (CoRAP)
    - Initial grounds of concern substance characterization/ nanomaterials
    - Synthetic amorphous silica (silicon dioxide) and silver

ECHA: Existing Tools for Regulation of Nanoscale Substances

Biocidal Products Regulation

- synthetic amorphous silicon dioxide, the first nanomaterial to go through the authorisation process as an existing active substance for use in biocidal products.

Sample of other Regulatory Activities

Other Countries/ Regulations

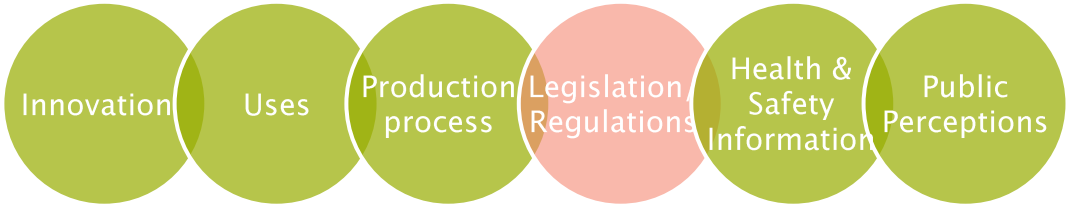
- Canada: New Substances Notification under CEPA 1999 (not on DSL); Nanotechnology Work Plan in progress
- France: Exposure registry, regulation requires reporting
- CPSC: Airborne nanoparticles from consumer products
  - Post market surveillance for "defective products"
- Australia: Notification and risk assessment for nanoforms as "new" substances under NICNAS
- Product safety regulations or guidance addressing nanomaterials in foods, food contact materials, medical devices, pharmaceuticals, and cosmetics

Regulatory Landscape

Emerging Trends

- Restriction of chemicals of concern in view of potential effects on susceptible populations
  - Chemicals in consumer products
  - Exposures to children
  - “New” hazards (e.g., nanomaterials, endocrine disruption)
  - New methods for toxicity testing (high throughput screening, in silico methods)
- Harmonization
- Sustainable chemistry (aka “green chemistry”)
- Collaboration between government regulatory agencies
- Transparency in supply chain: Implications for CBI

Framework for Risk Based Decisions



Identify product(s) and uses

Gather data

HAZARD IDENTIFICATION

Physical
Toxicological
Ecotoxicological

EXPOSURE CHARACTERIZATION

Workers
Consumers
Environment

Risk characterization
Identify uncertainties

LOW CONFIDENCE

HIGH CONFIDENCE

YES

Reduce uncertainty?

NO

Risks controlled?

NO

YES

Communicate decisions

Periodically re-assess

ENVIRON

Regulatory Compliance

- Although provisions for nanotechnology products and substances are not found in legislation/regulations, nanomaterials are currently considered chemical substances and subject to regulation
- From product design and development, consider the uses of your product and regulations that govern the end use of your product

> Nanomaterials are subject to regulations. Know your end uses and your customers' end uses.

Beyond Regulatory Compliance

- Keep abreast of drivers and opportunities to demonstrate safety and reduce uncertainty
  - New innovation
  - New science
  - New testing requirements / legislation/regulations
  - Risk management to control exposures
  - Changes in public perceptions and NGO pressures
- Apply risk assessment principles to reduce or eliminate hazards so far as reasonably practicable

> Proactive product stewardship provides opportunities to gain a market advantage and prepare for regulatory changes to come.

Stewardship: Think Big!

> No company should manufacture products or release by-products in ways that may cause harm, and neither can a company appear to have little knowledge of or control over the risks of its products and by-products, no matter how small those risks may actually be.

Joseph Rodricks, 1996

Thanks for your attention.

For more information, please contact:

Linda Dell, MS
ldell@environcorp.com

Ashish Jachak, PhD
ajachak@environcorp.com

Tracie Rose
trose@environcorp.com