Nano Risk Framework – An EHS Assessment Tool

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Nanotechnology:
The Future of EHS Regulatory Policy

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Nano Risk Framework

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ENVIRONMENTAL DEFENSE

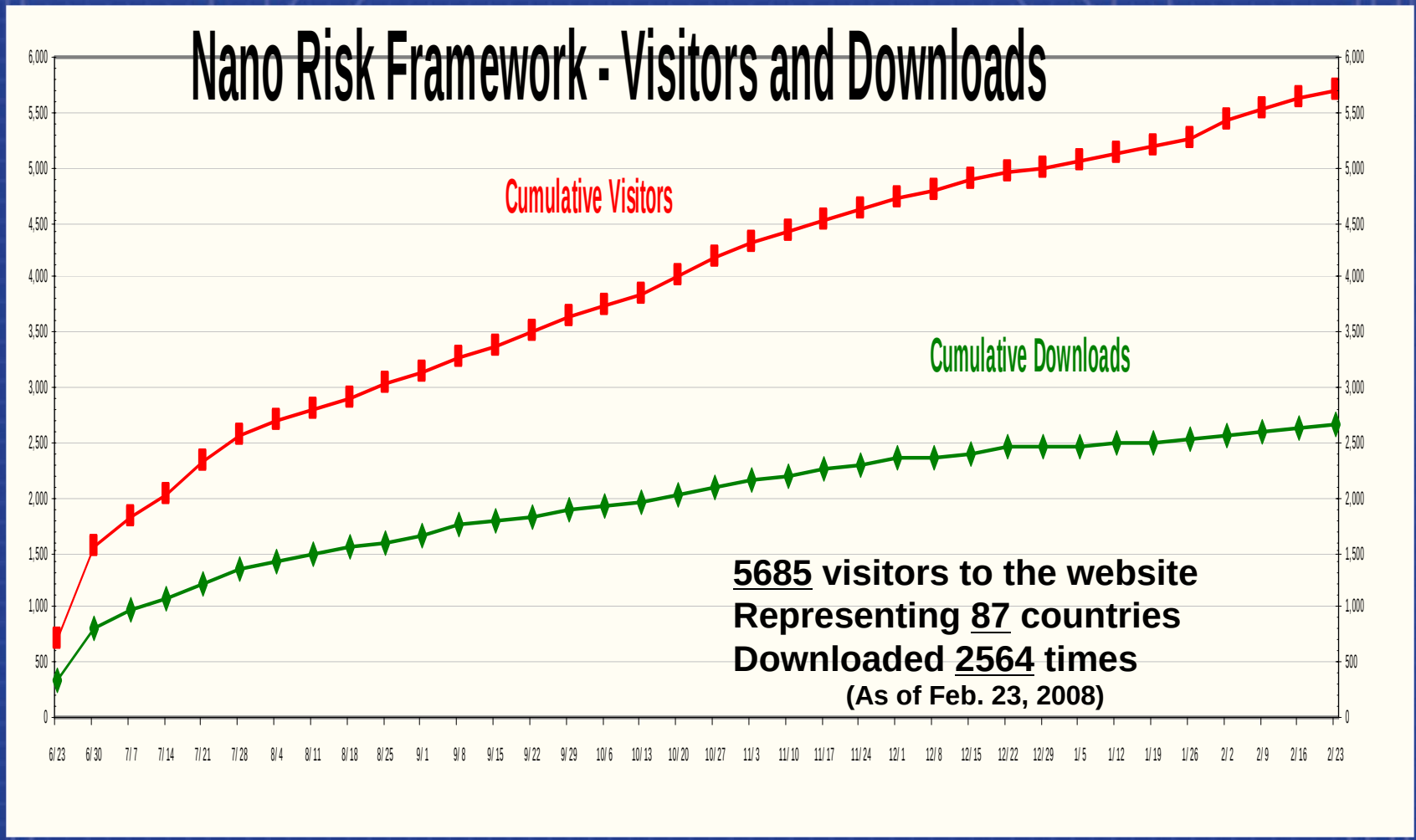
finding the ways that work

DUPONT

The miracles of science™

www.NanoRiskFramework.com

Global Impact



- Full Framework and worksheets are being translated into Chinese, French and Spanish
- Executive Summary has been translated into Portuguese
- Japanese translation under development

Website Visitors from 87 Countries

Algeria, Argentina, Australia, Austria, Azerbaijan, Belgium, Botswana, Brazil, Canada, Chile, China, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, Egypt, Estonia, Finland, France, Germany, Great Britain, Greece, Guatemala, Hong Kong, Hungary, India, Indonesia, Iran, Ireland, Israel, Italy, Japan, Kenya, Korea, Republic of, Kuwait, Latvia, Lebanon, Libyan Arab Jamahiriya, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Moldova, Monaco, Mongolia, Morocco, Netherlands, New Zealand, Nicaragua, Nigeria, Northern Mariana Islands, Norway, Pakistan, Peru, Philippines, Poland, Portugal, Qatar, Romania, Russian Federation, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Taiwan, Thailand, Turkey, Uganda, Ukraine, United Arab Emirates, United States, Uruguay, Venezuela, Vietnam, Yugoslavia, Zambia

Nano Risk Framework

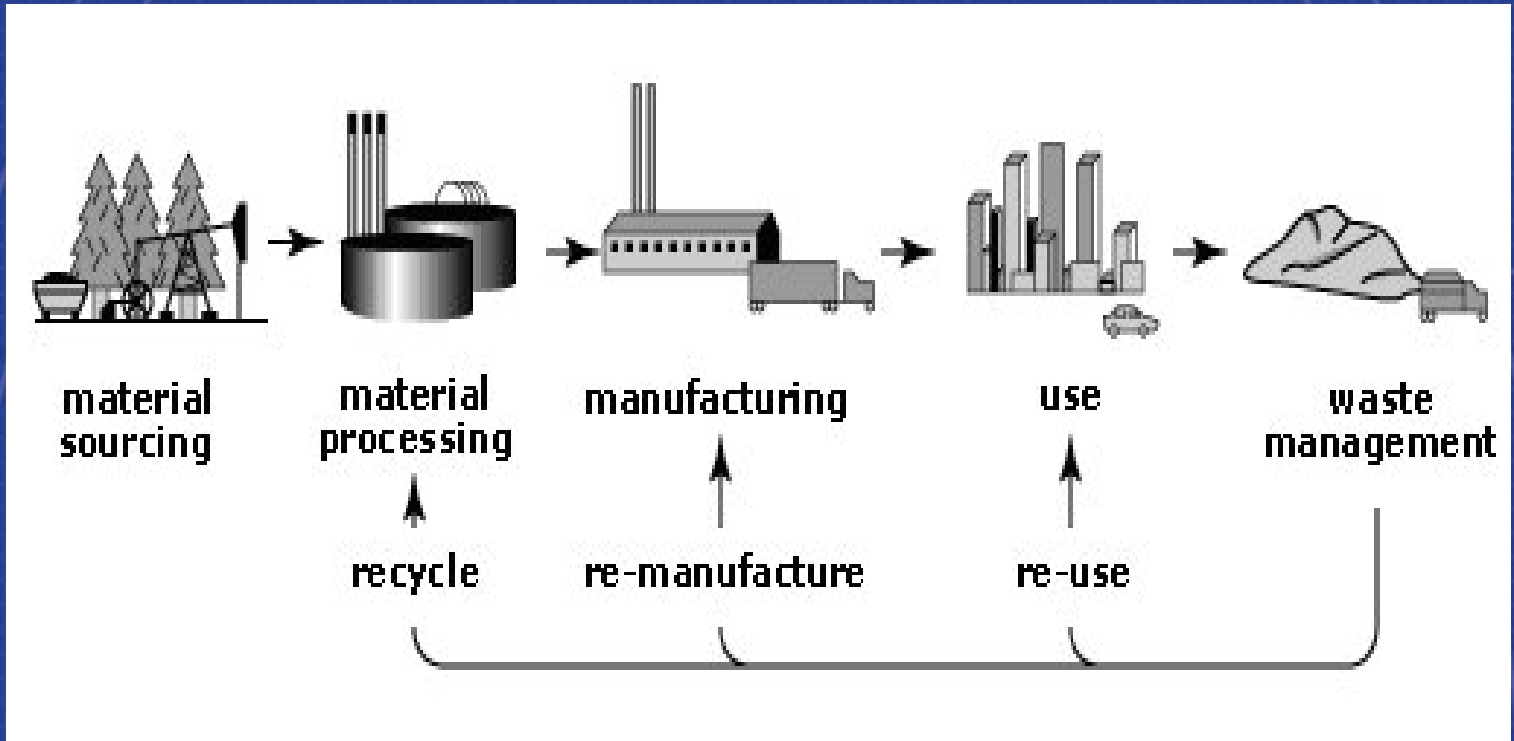
Objective: To develop and deliver a systematic and disciplined process for identifying, managing, and reducing potential environmental safety and health risks of engineered nanomaterials across all stages of a product's lifecycle.

Scope: Offers guidance on the **key questions** an organization should consider in developing applications of nanomaterials, and on the **information needed** to make sound risk evaluations and risk-management decisions.

Audience: Primary audiences are organizations such as companies and public and private research institutions that are **actively working** with nanomaterials and developing associated products and other applications. Framework can also be **useful to other stakeholders**, such as government officials, academia, financial institutions, and nongovernmental public-interest organizations.

Goal: Comprehensive, flexible, practical

Applying Life Cycle Thinking to Assessing Nanoscale Materials



(adapted from www.ami.ac.uk/courses/topics/0109_lct/)

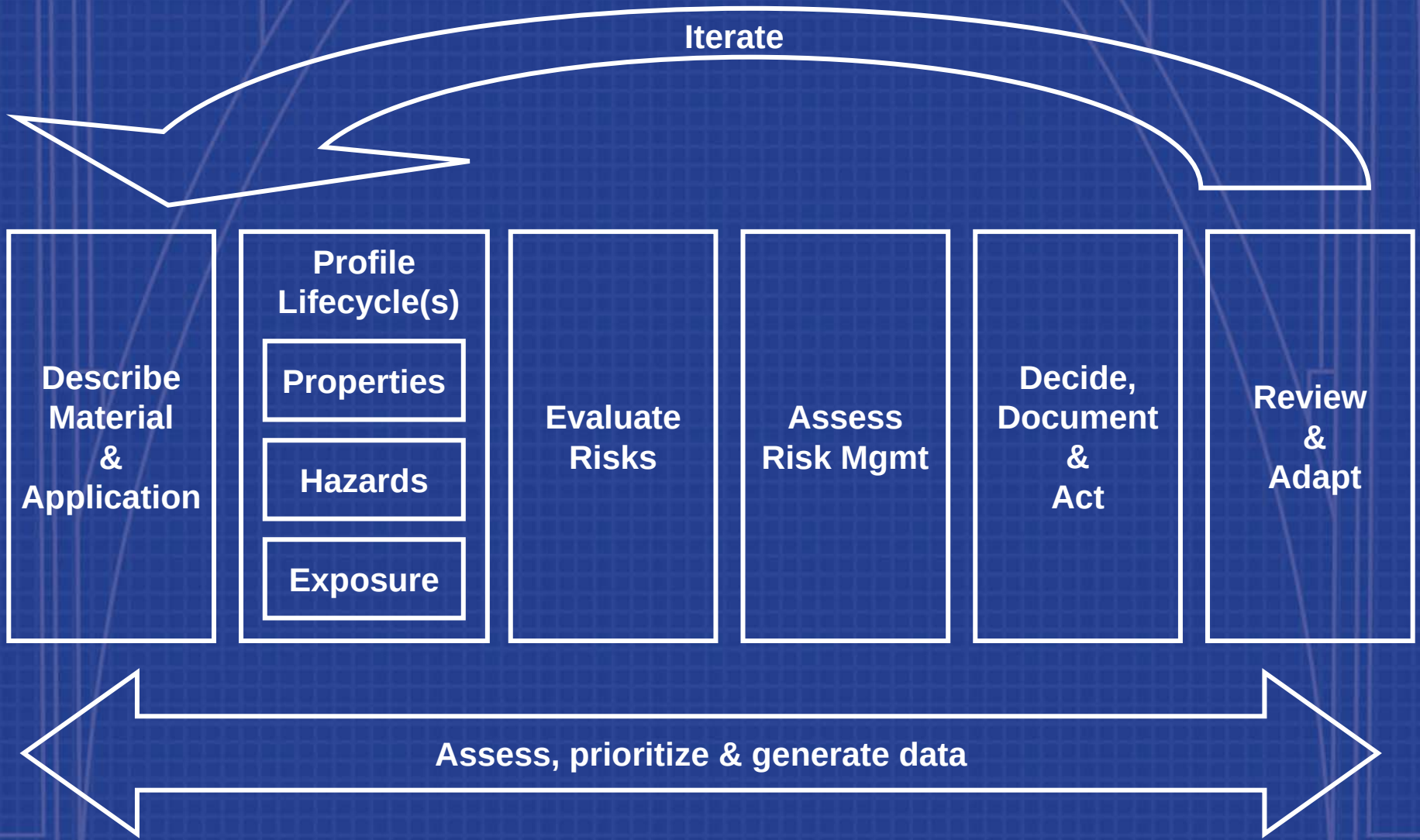
Comprehensive, Flexible and Practical

Comprehensive
Lifecycle Approach
Base Sets (Properties, Hazards, Exposure)
Cross-Functional Review
Review and Adapt

Flexible
Appropriate to Stage of Development
Data Generation
Conservative Assumptions
Appropriate Bridging
Expert Judgment

Practical
Familiar risk assessment paradigm
Typical development process
Complements product stewardship

Nano Risk Framework



1. Describe Material & Application

- Identify source and manufacturing process
- Review literature
- Identify reference, incumbent and bulk material counterparts
- **Describe material and expected applications, especially differences from incumbent and bulk materials**

2. Profile Lifecycle(s)

- Consider the material's full lifecycle within anticipated applications
- Consider multiple actors & branches
- Consider operations and material changes
- **Not a formal Life Cycle Analysis (LCA)**
- Develop Property, Hazard and Exposure profiles

“Base Sets” drive “Lifecycle Profiles”

- **Benchmark information needed for informed risk decisions**
  - **Not basis for a full hazard/risk assessment**
- Reference point for:
  - Factors to consider as early as possible in development
  - Type and amount of information expected by market launch
- Neither a ceiling nor a floor for info needs
- Analogous to sets used in other programs

Base Sets Categories of Information

- Physical-chemical properties
- Hazards
  - Health hazard
  - Environmental hazard
  - Environmental fate and behavior
  - Safety hazard
- Exposure

2A. Base Set Physical & Chemical Properties

- Particle Size
- Size Distribution
- Surface-Area
- Particle Density
- Solubility
- Dispersability
- Bulk Density
- Agglomeration State
- Chemical Reactivity
- Surface Reactivity
- Porosity
- Surface Charge
- Technical Name
- Commercial Name
- Common Form
- Chemical Composition
- Molecular Structure
- Crystal Structure
- Physical Form

2B. Base Set Health Hazard Data

- Short-term Toxicity:
  One or more of the following, depending on conditions:
  - Single-dose instillation study
  - 28-day inhalation study
  - 28-day repeated-dose oral toxicity test

  Each with full histopathology, over a 90-day observation period
- Skin sensitization/irritation
- Skin penetration
- Genetic toxicity tests

Triggers for Additional Testing

- High exposure potential
- High inherent hazard potential
- Results of base set studies
- **Significant changes**
  - **e.g., in production or use pattern**
- Compensating for lack of data or uncertainty

2B. Additional Health Hazard Data

- Biological fate and behavior
- Chronic (≥1 year) inhalation/ingestion toxicity
- Chronic dermal irritation/sensitization studies
- Developmental and reproductive toxicity
- Neurotoxicity studies
- More extensive genotoxicity studies
- Focused toxicity studies, e.g.:
  - Susceptibility studies — animal models
  - Allergenicity and immunotoxicity
  - Organ function bioassays

2B. Base Set Environmental Fate Data

- Environmental fate
  - Physical and chemical properties
  - Adsorption-desorption coefficients
  - Aggregation or disaggregation
- Persistence potential screen
  - Biodegradability test
  - Photodegradability / phototransformation
  - Stability in water (hydrolysis)
- Bioaccumulation potential screen

2B. Base Set Safety Hazard Data

- Flammability
- Explosivity
- Incompatibility
- Reactivity
- Corrosivity

2C. Base Set Exposure Data

- Manufacture
- Processing
- Use
- Distribution/storage
- Environmental releases
- Post-use management

3. Evaluate Lifecycle Risks

- Considering stage of lifecycle, position in value chain:
  - Review hazard and exposure profiles
  - Evaluate (quantify where possible) nature, magnitude and likelihood of identified risks
  - Identify knowledge gaps
- Develop plan to fill data needs or develop “reasonable worst-case assumptions” for missing data elements

4. Assess Risk Management

- Determine needed level of protection to be achieved through risk management
- Assess adequacy of current management & engineering controls to address identified potential risks
- Determine best risk management options
- **Develop plans for risk management, monitoring, compliance & reporting**

5. Decide, Document & Act

- Review risk evaluation and risk management assessment
- Consider business, legal and stakeholder issues
- Decide whether and, if so, how to proceed
- Implement risk management, monitoring & compliance processes
- Determine & initiate additional data collection as needed
- Determine product review cycle
- **Document and report decisions and actions**

6. Review and Adapt

- Conduct reviews on a regular basis and as needed in response to significant changes in hazard and exposure information, production volume, and use profile:
  - Evaluate new data or changes
  - Review and revise as needed risk evaluation and risk management decisions
- **Adapt risk management and collect additional information as appropriate**
- Document and report any new decisions and actions

OUTPUT WORKSHEET

An editable version of this Output Worksheet is available at www.NanoRiskFramework.com

Nanomaterial Risk Assessment Document — [nanomaterial]

Section 1: Describe Material and Its Applications
Develop basic descriptions — general overviews — of the nanoscale material and its intended uses.

General Overview: [1]

Material Description:
Material source or producer:
Manufacturing process:
Appearance:
Chemical composition:
Physical form/shape:
Concentration:
Size distribution:
Solubility:
State of aggregation or agglomeration:
Material CAS number (if applicable):

Material	CAS Number	Composition

Main applications (current or expected):

Stage of development:

General physical and mechanical properties of this material:

Past experience with this material or a similar material:

Potential benefits/positives of the material:

Potential risks/negatives of the material:
Health:
Environmental:

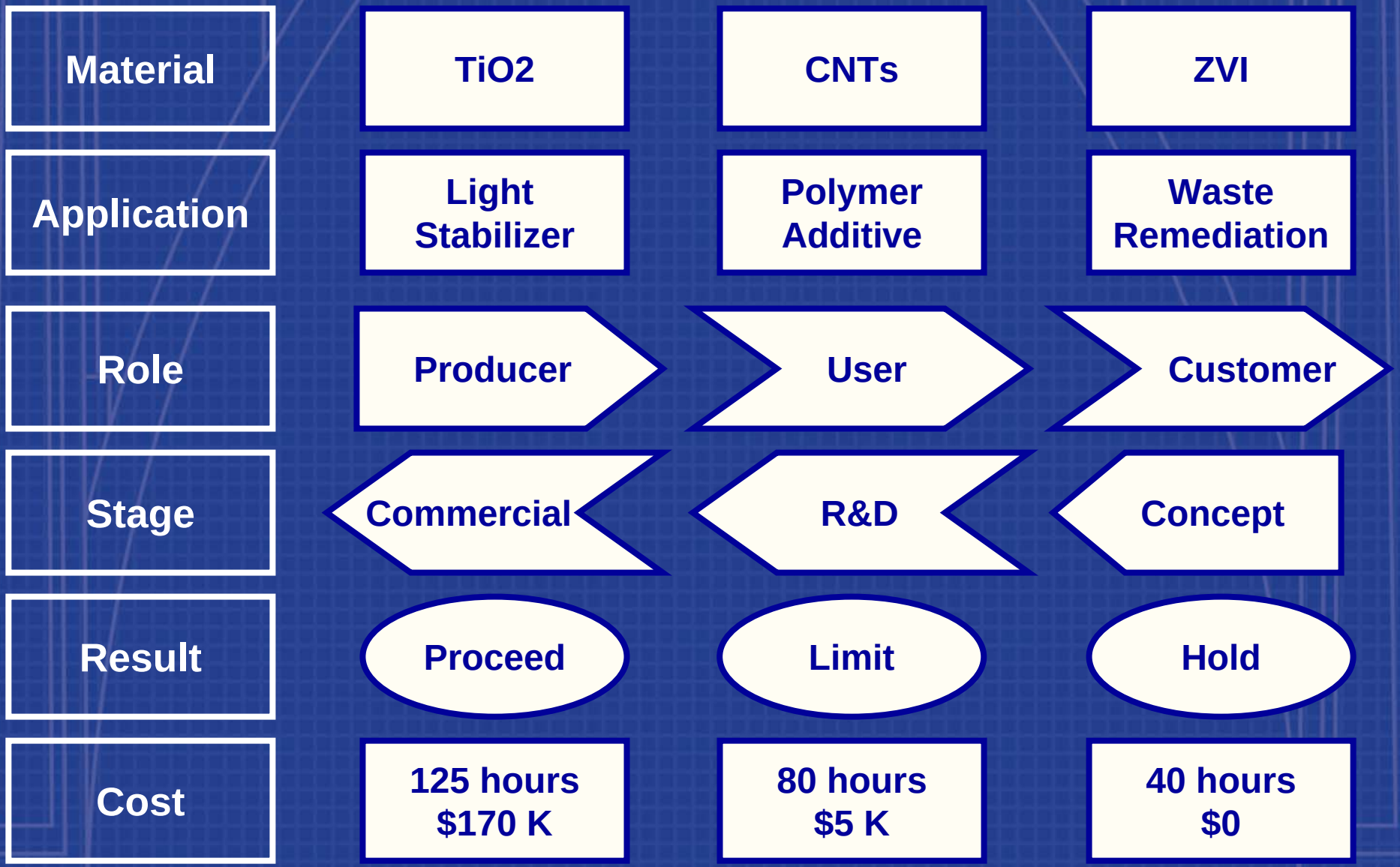
Sources of additional information:

[1] The general overview should contain descriptions sufficient to guide development of more detailed profiles of the material's properties related to hazard and exposure potential at various lifecycle stages (such as manufacture, use, and end-of-life). This overview should be developed from information in the possession of the user or available in the literature.

Output Worksheet

- Organize
- Record
- Share

Case Studies



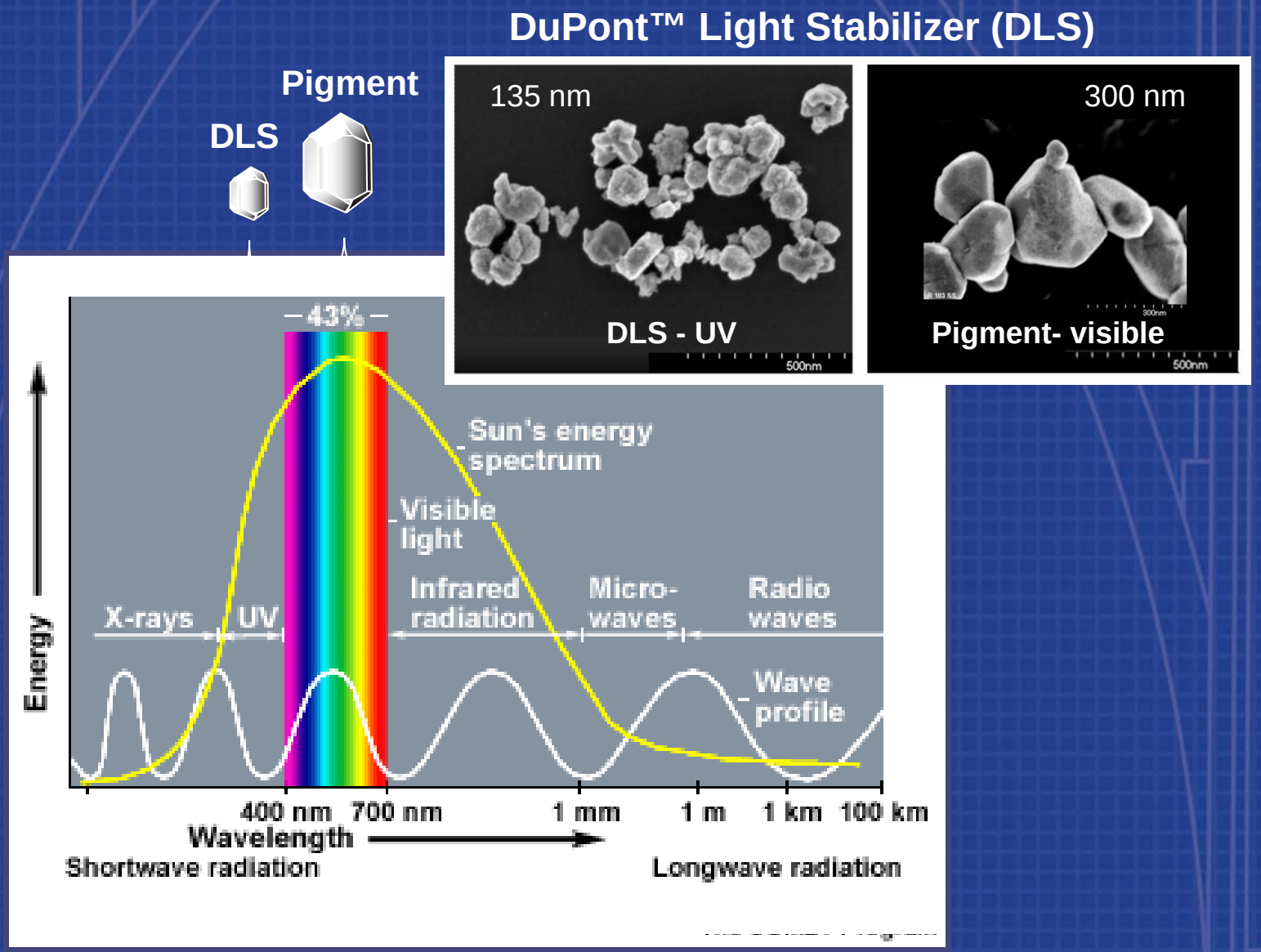
Nanoscale Titanium Dioxide Particles in DuPont (TM) Light Stabilizer 210 Help Protect Plastics from Sun Damage

First Product Developed Using DuPont-Environmental Defense Nano Risk Framework

WILMINGTON, Del., Oct. 15, 2007 – DuPont today introduced DuPont (TM) Light Stabilizer 210, a product designed as sun protection for plastics. The product uses extremely small particles of titanium dioxide to efficiently absorb ultraviolet light, protecting plastic and anything it covers from the sun's damaging rays. Because a sizeable percentage of titanium dioxide particles in the product are nanoscale, it was selected as a demonstration case for application of the Nano Risk Framework that DuPont and Environmental Defense introduced in June. The Framework is a systematic and disciplined process to evaluate and address the potential risks of nanoscale materials.

DuPont(TM) Light Stabilizer 210 offers protection from the sun's UV rays for plastics used in products such as playground equipment, toys, outdoor furniture and construction components.

Particle size is optimized to scatter light



Summary

As an assessment tool, the Framework provides a systematic and disciplined process for identifying, evaluating and addressing potential EHS risks of nanoscale materials across the product's lifecycle.

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