Safe Development of Nanotechnology

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2010 Guidance

Nanotechnology creates a wide range of opportunity for innovation in areas such as biomedical devices, improved electronic devices, clean energy technology, and materials engineering.

At the same time, there are indications of potential harm from certain exposures and releases of engineered nanoparticles (ENPs).

Preventing that harm is an important part of an agenda to capture the benefits of nanotechnology. A weak program of prevention will raise the risk of liabilities and possibly rules that inhibit innovation.

An effective prevention approach can result in better rules as they are adapted or developed. The best rules will be based on knowledge of best practices.

Program for worker safety

Evaluation of the potential exposures to ENPs:

- where they might become free to be inhaled or otherwise absorbed during synthesis, transfer, delivery of pre-manufactured ENPs, storage, use.
- Include ENP residues in equipment, used filters, and unintended releases.
- ENPs have the potential for enhanced mobility in air: evaluate air movement near potential release points.
- Nanomaterial air concentrations may be measured through aerosol sampling, airborne surface area analysis, and particle number measurement.

Preventive Materials Selection and Process Design

- Carbon nanotube toxicity may be reduced by modifying fiber length or mitigated by dispersion to prevent aggregation.
- Biological oxidative stress may be correlated with specific surface area and certain metal ions – knowing the expected electronic energy level s in the nanoparticle structure can be used to predict if it will remove antioxidants from cells or generate reaction oxygen species.
- Hydrophilicity and neutral charge have been found to be “conducive to low cytotoxicity and reduced inflammation”.
- Toxicity has been reduced by modifying surfaces and using coatings.
- Addition of molecular groups to nanoparticles can significantly alter bioimpact.
- *Product designers should familiarize themselves with this new and rapidly developing literature.*
- Nano particles and fibers generated during machining: dry cutting without emissions controls creates risk for exposure compared to wet cutting.

After prevention, control

- Design engineering controls for potential release points, including containment and local ventilation to prevent release of the ENPs into the workplace, using High Efficiency Particulate Air filters.
- Use these filters as well at all environmental air emission points, to prevent release to the environment.
- NIOSH expects that “for most processes and job tasks, the control of airborne exposure to nano-aerosols can be accomplished using a variety of engineering control techniques similar to those used in reducing exposure to general aerosols”.

Personal Protection

- Clothing appropriate for wet-chemistry laboratory operations (closed-toed shoes, long pants without cuffs and long sleeved shirt, laboratory coats, proper eye protection, and nitrile or latex gloves).
- See NIOSH Respirator Selection Logic, include training, fit testing, evaluating respirator impact on ability to perform work, monitoring, and respirator maintenance.
- In cases where respirators are not required but precaution suggests their use, dust masks or disposable respirators with an N95 or higher filter rating are recommended.
- When respirators are necessary to protect worker health, OSHA's respiratory protection standard (29 CFR 1910.134) triggers medical evaluation requirements.

Prevent Emissions

- Contaminated waste, disposal of liquids, and potential air releases. Washing of items or equipment.
- Will waste water systems, stacks, capture ENPs?
- Will they remain safely bound in treatment residues such as sludge, filters, or absorption media?
- Best practices: prevent any drain discharge of ENPs, implement safe-change procedures for used HEPA filters, wet cleaning, clean-in-place, enclosed transfer of materials.

Waste Management

- Establish protocols to ensure the proper handling of wastes contaminated by ENPs, such as wipes, PPE, workclothing, and any material in which ENPs have become trapped, could break free, or leach out.
- Enclose all ENP containers, including waste, with secure caps or covers, and instruct handlers, through appropriate labeling, in preserving containment controls.
- Ensure waste transporters are aware that they are carrying waste containing ENPs, and include in waste management contracts assurances that the waste material from your facility will be handled and disposed of safely, such as that the ENPs will be fixed in solid media or enclosed until destruction or permanent isolation.
- Before sending for incineration, determine if that method will effectively destroy the waste.

Post Use Liability

- Warning provides legal protection.
- Thinking through the life cycle of the product, and who faces risks of exposure down the line, is a starting point for assessing where disclosure may be advisable.
- Place yourself in the context of the product recipient and ask, “would I wish to be informed of the presence of this material?”

EPA Actions

"To ensure that nanoscale materials are manufactured and used in a manner that protects against unreasonable risks to human health and the environment, EPA is pursuing a comprehensive regulatory approach under TSCA including:

- Premanufacture notifications for new nanomaterials.
- An information gathering rule on new and existing nanomaterials."

Pre-Manufacture Notices

"Since 2005, EPA has received and reviewed over 160 new chemical notices under TSCA for nanoscale materials, including carbon nanotubes, and that number will increase over time. The Agency has taken a number of actions to control and limit exposures to these chemicals, including:

- Limiting the uses of the nanoscale materials,
- Requiring the use of personal protective equipment and engineering controls,
- Limiting environmental releases, and
- Requiring testing to generate health and environmental effects data.

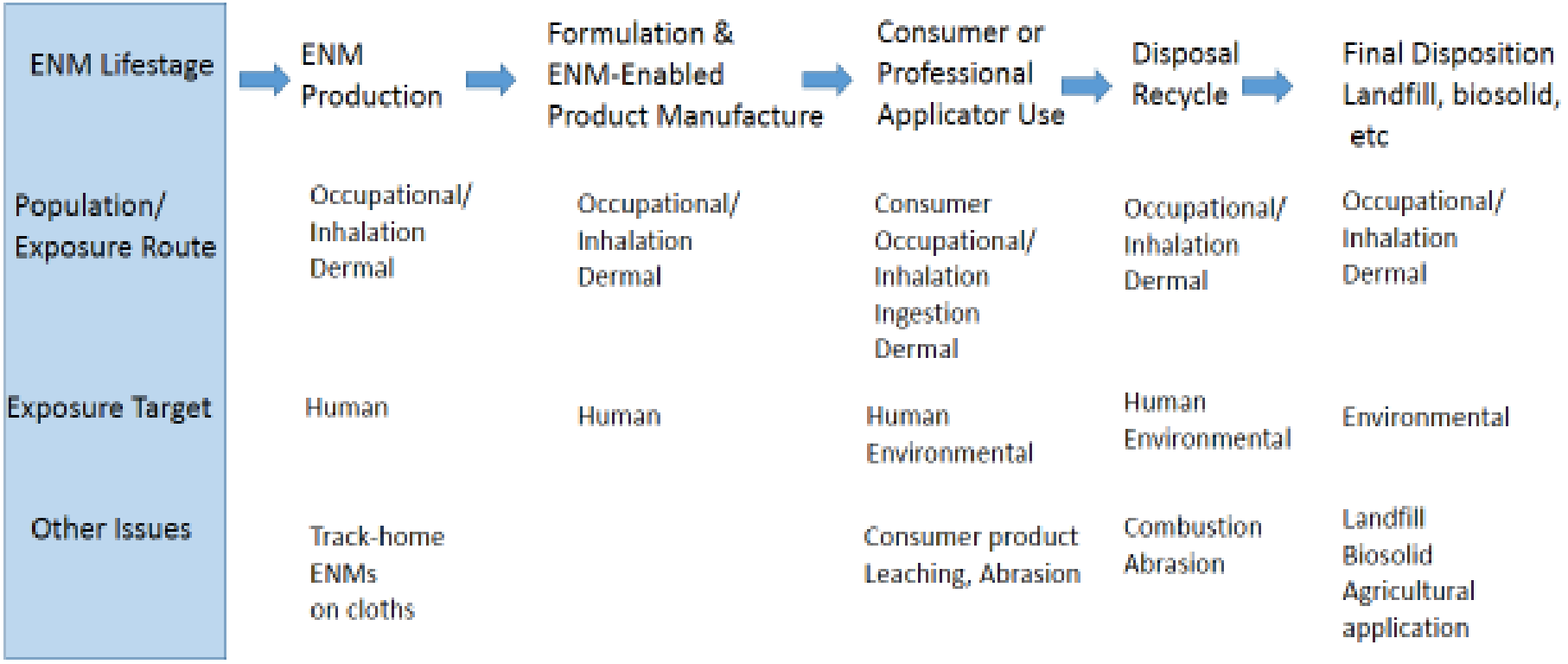
EPA has permitted limited manufacture of new chemical nanoscale materials through the use of consent orders or Significant New Use Rules under TSCA. The Agency has also allowed the manufacture of new chemical nanoscale materials under the terms of certain regulatory exemptions, but only in circumstances where exposures were tightly controlled to protect against unreasonable risks (using, for example, the exposure and environmental release limitations discussed above)."

Coordination with Canada and OECD

- How manufactured nanomaterials should be categorized for purposes of testing, read across/ Structure-Activity Relationships (SAR), risk assessment and risk management.
- Physical-chemical characterization; fate, exposure; ecotoxicity; human health toxicity; exposure assessment; risk assessment and risk management.

From the Background Document for 2014 OECD meeting

Framework for Exposure Assessment Based on ENM Lifecycle



Information Gathering Rule

April 6, 2015 – "As part of the Agency's effort to ensure a more comprehensive understanding of nanoscale materials in commerce, EPA proposed one-time reporting and recordkeeping requirements under TSCA SECTION 8(a)."

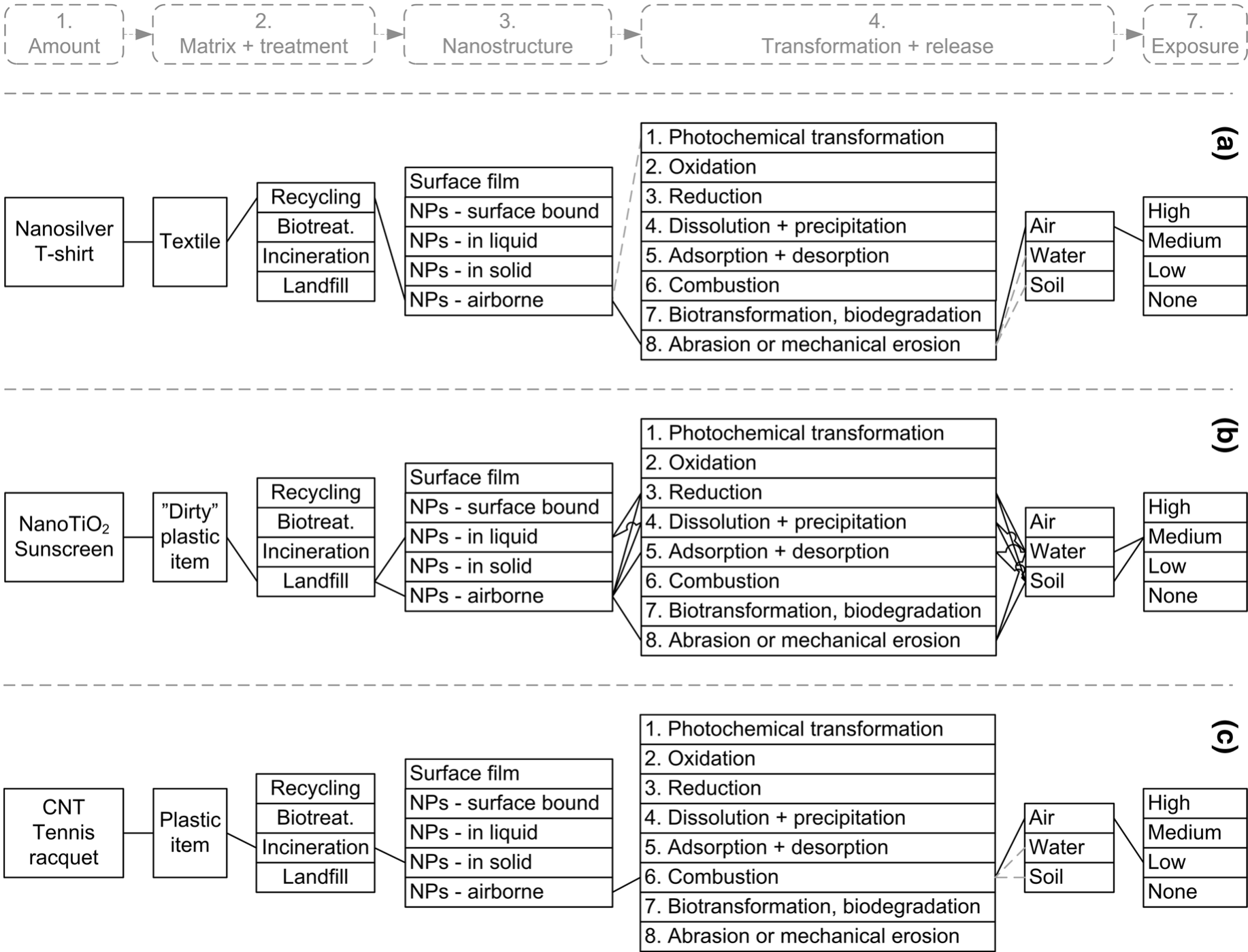
Companies that manufacture certain chemical substances already in commerce as nanoscale materials would have to notify EPA of information including production volume, methods of manufacture and processing, exposure and release information, and available health and safety data.

"This proposed rule is not intended to conclude that nanoscale materials as a class, or specific uses of nanoscale materials, are likely to cause harm to people or the environment. Rather, EPA would use information gathered through this reporting rule to determine if any further action under TSCA, including additional information collection, is needed."

Example: Nano in waste

"Environmental exposure assessment framework for nanoparticles in solid waste", Boldrin, Hansen, et al. *Jrnl Nanoparticle Research*, May 2014.

- Framework for the systematic assessment of ENM exposure during nanowaste management.
- Nanosilver polyester textile, nanoTiO2 sunscreen lotion and carbon nanotube tennis racquets.
- The potential global environmental exposure of ENMs associated with these three products is estimated 0.5–143 Mg/year, characterized qualitatively as medium, medium, low, respectively.


1. Amount
2. Matrix + treatment
3. Nanostructure
4. Transformation + release
7. Exposure
(a)
Nanosilver T-shirt
Textile
Recycling
Biotreat.
Incineration
Landfill
Surface film
NPs - surface bound
NPs - in liquid
NPs - in solid
NPs - airborne
1. Photochemical transformation
2. Oxidation
3. Reduction
4. Dissolution + precipitation
5. Adsorption + desorption
6. Combustion
7. Biotransformation, biodegradation
8. Abrasion or mechanical erosion
Air
Water
Soil
High
Medium
Low
None
(b)
NanoTiO2 Sunscreen
"Dirty" plastic item
Recycling
Biotreat.
Incineration
Landfill
Surface film
NPs - surface bound
NPs - in liquid
NPs - in solid
NPs - airborne
1. Photochemical transformation
2. Oxidation
3. Reduction
4. Dissolution + precipitation
5. Adsorption + desorption
6. Combustion
7. Biotransformation, biodegradation
8. Abrasion or mechanical erosion
Air
Water
Soil
High
Medium
Low
None
(c)
CNT Tennis racquet
Plastic item
Recycling
Biotreat.
Incineration
Landfill
Surface film
NPs - surface bound
NPs - in liquid
NPs - in solid
NPs - airborne
1. Photochemical transformation
2. Oxidation
3. Reduction
4. Dissolution + precipitation
5. Adsorption + desorption
6. Combustion
7. Biotransformation, biodegradation
8. Abrasion or mechanical erosion
Air
Water
Soil
High
Medium
Low
None

Significant New Use Rules

On September 2, 2014, the U.S. Environmental Protection Agency (EPA) promulgated final significant new use rules (SNUR) under Section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 36 chemical substances that were the subject of premanufacture notices (PMN).

* Multi-walled carbon nanotubes,
* Multi-walled carbon nanofibers,
* Carbide derived nanocarbon.

Persons who intend to manufacture or process any of these 36 chemical substances for an activity that is designated as a significant new use must notify EPA at least 90 days before commencing that activity.

On February 2, 2015, SNURs for 27 chemical substances, effective April 3.

Polymer of terephthalic acid and ethyl benzene with multi-walled carbon nanotube is subject to a Toxic Substances Control Act (TSCA) Section 5(e) consent order requiring:

- Use of personal protective equipment involving impervious gloves and protective clothing (where there is a potential for dermal exposure) and a (NIOSH)-certified respirator with N-100, P-100, or R-100 cartridges (where there is a potential for inhalation exposure);
- Submission of physical-chemical data within nine months;
- Submission of human health testing prior to exceeding the confidential production volume limit specified in the consent order;
- Processing and use of the substance only for the confidential use specified in the consent order; and
- No use of the substance resulting in releases to surface waters.
- **The SNUR designates as a "significant new use" the absence of these protective measures.** The SNURs require persons who intend to manufacture (including import) or process any of these 27 chemical substances for an activity that is designated as a significant new use by the rule to notify EPA at least 90 days before commencing that activity.

Questions

- OSHA requires that hazards be identified and communicated. If your SDS does not explain new potential hazards, are you off the hook?
- RCRA requires identification of haz waste characteristics. If nanoengineering creates a reactive dust, are you managing the waste as a characteristic haz waste?
- CWA may result in effluent toxicity testing.
- Does anyone in the chain of production or use – or neighbors - facing risk of exposure have a cause of action for failure to warn or dereliction of general duty?
- Is there liability for post-use disposition costs or cleanup?
- Do emergency responders, visitors, inspectors face risks?

Keeping up

- From Lynn Bergeson's Blog: http://nanotech.lawbc.com/

- The Center for Food Safety (CFS) and others filed suit on December 16, 2014, in the U.S. District Court for the District of Columbia against the U.S. Environmental Protection Agency (EPA) over its failure to regulate novel nanomaterial pesticides. CFS filed a legal petition in 2008 requesting that EPA regulate nanosilver products as pesticides… "nearly six years later the agency has still failed to respond to Plaintiffs' 2008 Petition, a failure that violates the mandates of the Administrative Procedure Act (APA)… hundreds of new pesticidal nano-silver products have reached the market without any pesticide oversight from EPA."

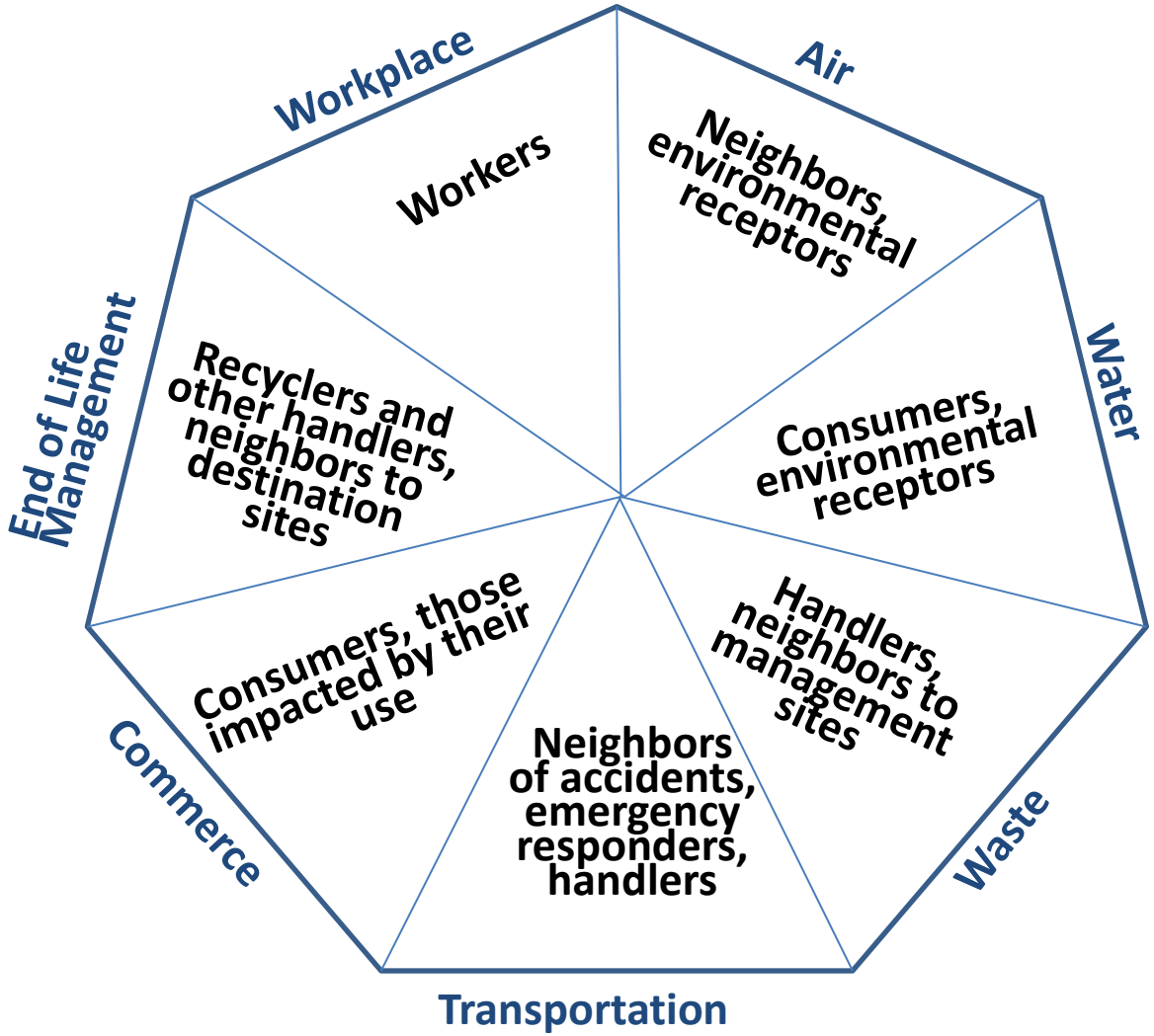
- The USDA National Organic Program announced March 24 that "No engineered nanomaterial will be allowed for use in organic production and handling unless the substance has been: (1) petitioned for use; (2) reviewed and recommended by the National Organic Standards Board (NOSB); and (3) added to the National List of Allowed and Prohibited Substances through notice and comment rulemaking".

Indication of Things to Come?

- In 2013 France became the first country in Europe to require manufacturers to identify the use of “substances with nanoparticle status” that they produce, import, distribute, or formulate.

- In March 2015 the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) published an Opinion concerning exposure to silver nanoparticles that states the research that has been carried out to examine the potential health and environmental effects of silver nanoparticles is still “insufficient to allow the health risks to be assessed…” and recommends limiting the marketing of products containing silver nanoparticles to applications whose advantages have been clearly demonstrated.

The Seven-Sided Universe and
the Incidental Stakeholders living in each Dimension



Join the Discussion

- Receive and Post Information on “Safe and Green Nano”

http://www.internano.org/mailman/listinfo/safe-and-green-nano

Send us comments on “Considerations for the Safe Development of Nanotechnology” – will need to be updated.

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