Alternatives Assessment 120 Webinar:

Alternatives Assessment for Engineered Nanoparticles

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FACILITATED BY: JOEL TICKNER, SCD

JOEL_TICKNER@UML.EDU
LOWELL CENTER FOR SUSTAINABLE PRODUCTION, UMASS LOWELL

** If you would like to ask a question or comment during this webinar please type your question in the Q&A box located in the control panel.*

Goals

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- Continuing education and dialog
- To advance the practice of alternatives assessment for informed substitution across federal, state, and local agencies through networking, sharing of experiences, development of common approaches, tools, datasets and frameworks, and creation of a community of practice.

Purpose of this call

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- Chemical alternatives assessment processes were developed based on characteristics and endpoints of concern for traditional bulk chemicals.
- Engineered nanomaterials present a number of benefits over traditional chemicals for specific functional uses.
- Engineered nanomaterials add a new set of challenges given their unique physical characteristics, potentially novel mechanisms of toxicity, and minimal toxicity data to evaluate hazards.
- This webinar presents some challenges of applying chemicals alternatives assessment to engineered nanomaterials including a study of application of the GreenScreen to nanosilver.

Speakers

Lowell Center for Sustainable Production
UNIVERSITY OF MASSACHUSETTS LOWELL

- Molly Jacobs, Lowell Center for Sustainable production
- Dr. Jennifer Sass, Natural Resources Defense Council
- Dr. Lauren Heine, Clean Production Action

Discussion Questions

- What are the specific challenges of conducting alternatives assessments for engineered nanomaterials?
- What are the opportunities for integrating nanomaterials into existing alternatives assessment processes. What modifications to existing processes might need to be made?
- Are there new data types or design principles that can help guide alternatives assessment for engineered nanomaterials?

Webinar Discussion Instructions

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- Due to the number of participants on the Webinar, all lines will be muted.
- If you wish to ask a question, please type your question in the Q&A box located in the drop down control panel at the top of the screen.
- All questions will be answered at the end of the presentations.

Alternatives Assessment & Nanomaterials: Needs, Challenges & Opportunities

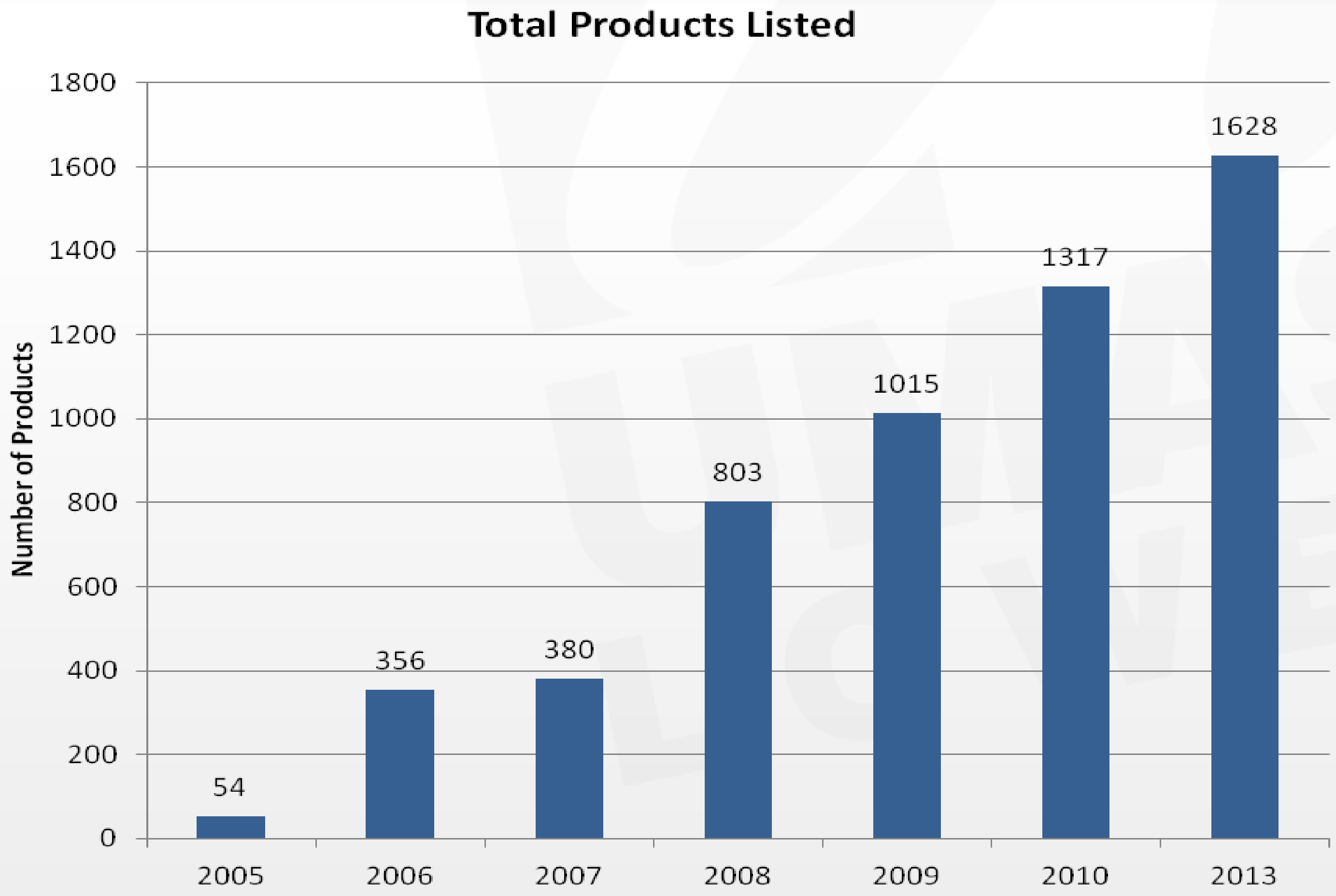
Molly Jacobs
Lowell Center for Sustainable Production
University of Massachusetts Lowell

Engineered Nanomaterials

What are they?

- Engineered nanomaterials: at least one primary dimension that is less than 100 nanometers
  - carbon compounds, metals and/or metal oxides, composites and dendrimers
- By 2020, NSF estimates that nanotechnology will:
  - have a $3 trillion impact on the global economy
  - employ 6 million workers in the manufacture of nanomaterial-based products – 2 million of which likely manufactured in the United States

Dramatic Growth in Engineered Nanomaterial-Based Consumer Products

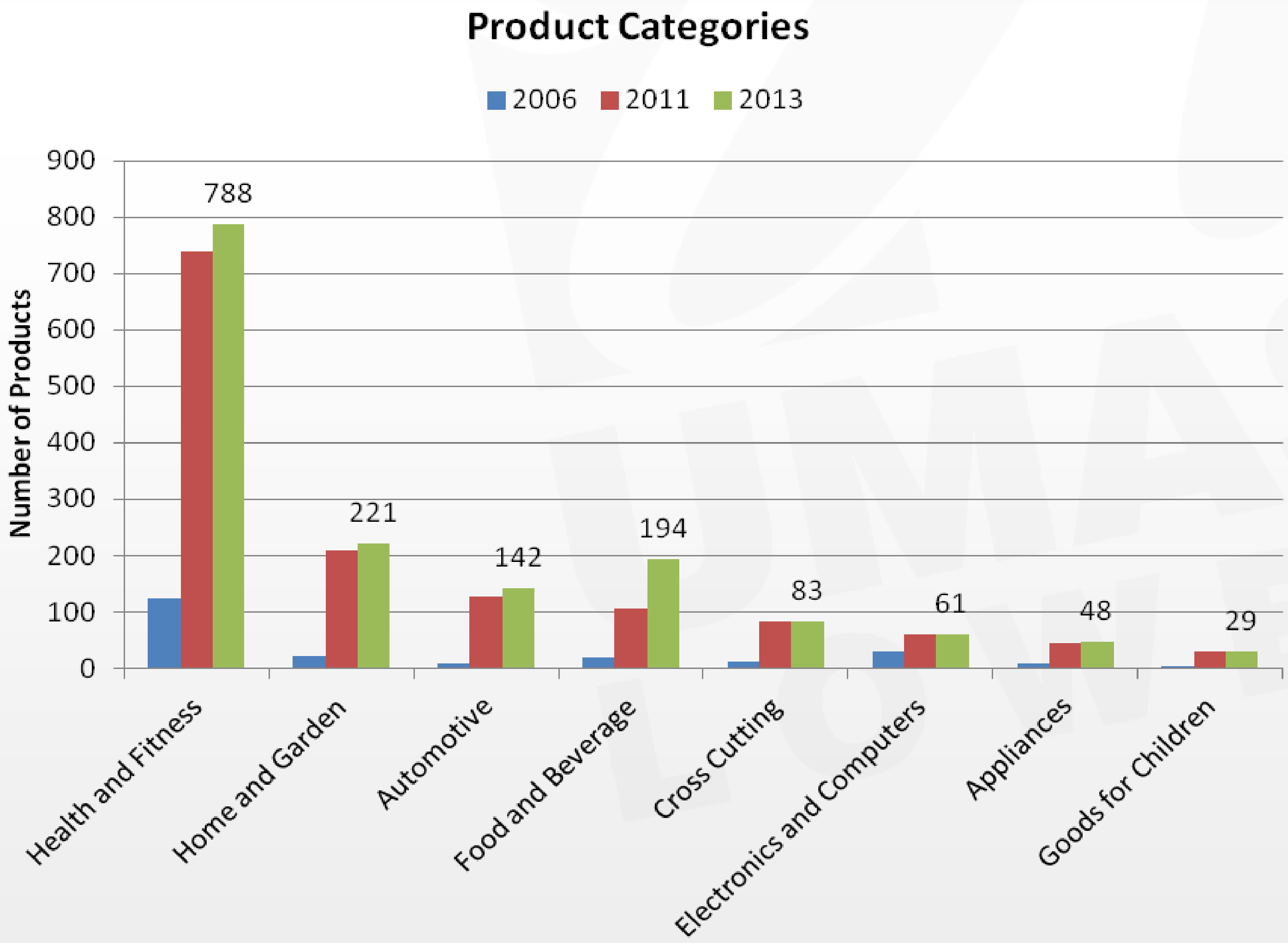


Source: Project on Emerging Technologies, Consumer Products Inventory

Learning with Purpose

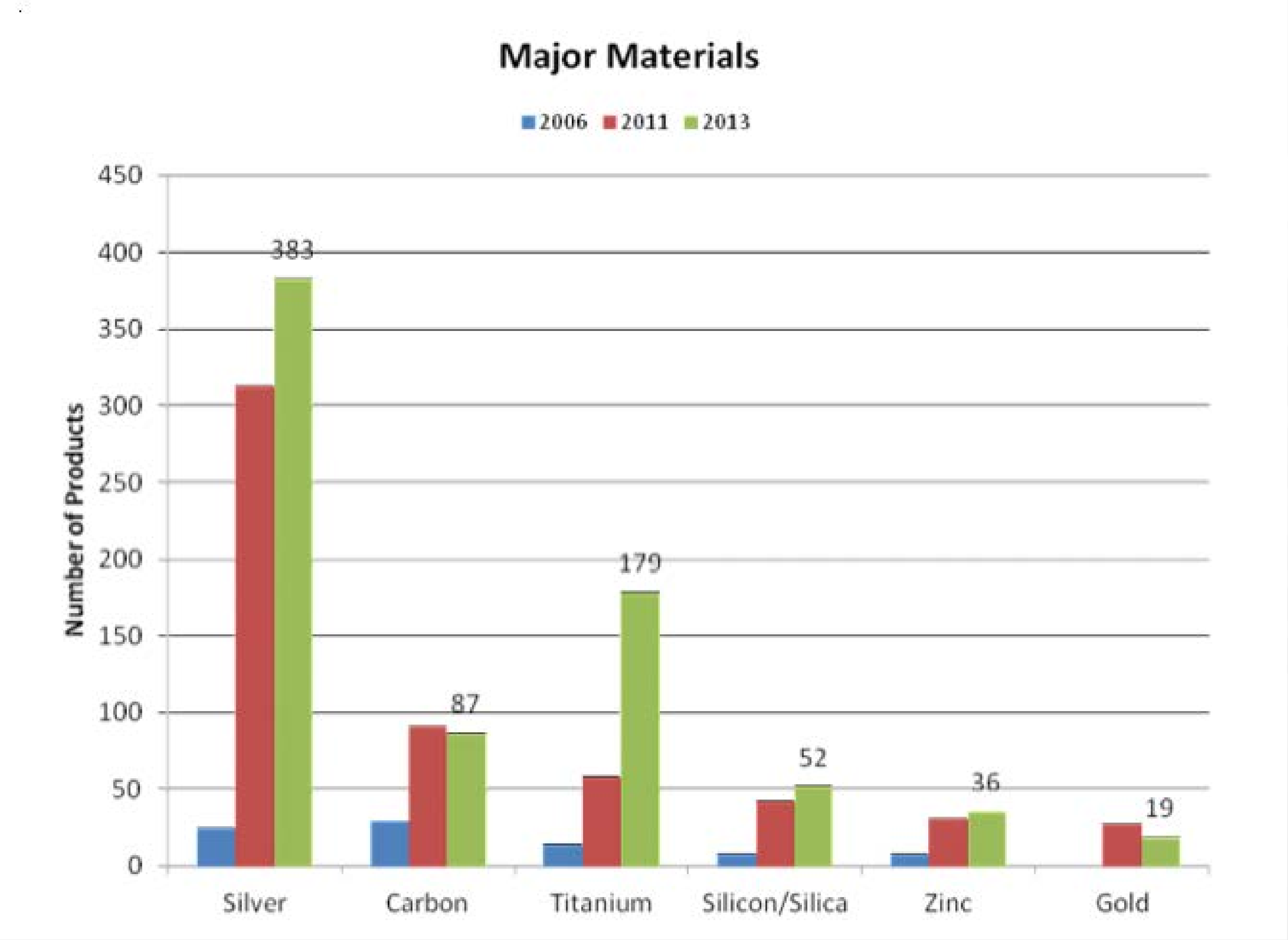
UMASS LOWELL

Engineered nanomaterials: in what products?



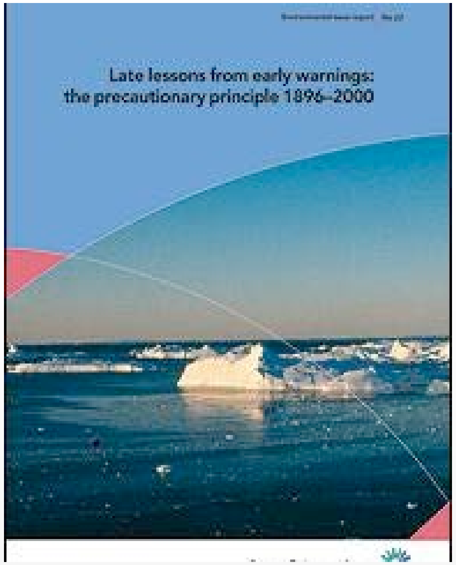
Source: Project on Emerging Technologies, Consumer Products Inventory

Using what types of engineered nanomaterials?



Source: Project on Emerging Technologies, Consumer Products Inventory

Lessons from the Past



Late Lessons from Early Warnings (2001, EEA)

- 14 case studies where early warnings were ignored, including asbestos, PCBs, MBTE, benzene

Are we destined to repeat the same mistakes with engineered nanomaterials?

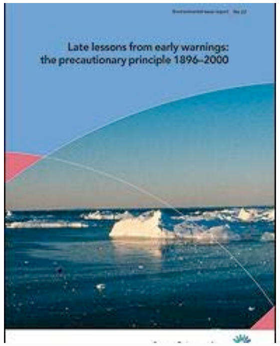
Evidence of Harm: Environmental & Human Health

Example: CNTs

- Pulmonary Fibrosis [MWCNTs & SWCNTs]
- Cancer (lung tumor promotion; possibly mesothelioma) [MWCNTs]
- Aquatic Toxicity (e.g. *Daphnia magna*) [MWCNTs & SWCNTs]

Sources: Mercer, et al. *Part Fibre Toxicol* 2010;7:28. Mercer, et al. *Part Fibre Toxicol* 2013;10(1):33. Sargent, et al. *The Toxicologist* 2013; 130:A457. Poland et al, *Nat Nanotechnol* 2008;3:423-428. Takagi, et al. *J Toxicol Sci.* 2008;33(10: 105-116. Petersen, et al. *Env Sci Technol* 2011; 45(23):9837-9856.

One of the 12 Lessons: Evaluate Alternative Solutions



- Lesson summed up as: “Don’t become so enamored by a new technology that you are blinded to alternative solutions”*
- Instead, we need to ask: what chemical, material or process can achieve the same function and is safe for health, the environment, and is economically feasible?

*Source: Hansen S., et al. *Nature Nanotechnology.* 2008 Aug;3(8):444-7.

Alternatives Assessments of Nanomaterials: The Need

Example: CNTs

- During chemical substitution evaluations:
  - Might we be risking regrettable substitutions?
    - MWCNTs for brominated flame retardants
    - MWCNTs for tributyltin in antifouling paints
- During the design phase:
  - Comparing different CNTs or alternatives

Principles of Design for SAFER Nanotechnology
Size, Surface & Structure: Diminish or eliminate the hazard by changing the size, surface or structure of the nanoparticle while preserving the functionality of the nanomaterial for the specific application
Alternative Materials: Identify either a nano or bulk safer alternative that can be used to replace a hazardous nanoparticles
Functionalization: Add additional molecules (or atom) to the nanomaterial to diminish or eliminate the hazard while preserving the desired properties for a specific application
Encapsulation: Enclose a nanoparticle within another less hazardous material
Reduce the quantity: Where the above principles can not be used, and use is necessary, investigate opportunities to use smaller quantities.

Source: Morose, G. *J Cleaner Prod.* 2010;18:285-289.

Alternatives Assessments of Nanomaterials: The Challenge

Which one? Are data available?

Example CNTs:

- Tens of thousands of different type of CNTs
  - No single CAS #

- Hazard level depends of specific physical-chemical characteristics:

- Size
- Structure
- Surface area
- Chemical characteristics
- Charge
- Reactivity
- Solubility
- Agglomeration potential
- Oxidative generation potential

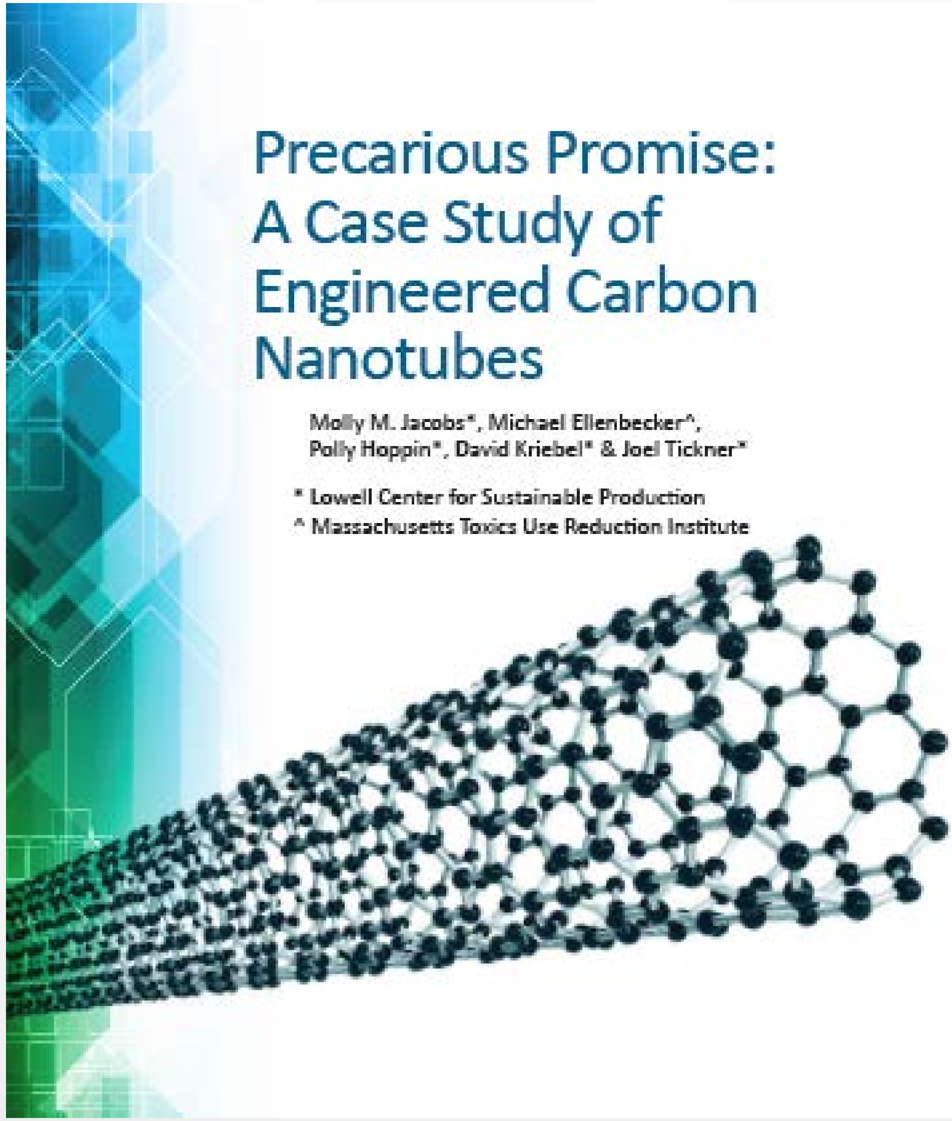
Alternatives Assessment of Nanomaterials: The Opportunity

- Emerging hazard data sources: High-throughput toxicity screening
  - Rapidly screen for toxicity of nanomaterials
  - Testing batches of CNTs have shown variations in specific cellular mechanisms that are consistent with pulmonary effects observed in animal models*
- State & Federal programmatic/regulatory developments (examples):
  - NIOSH's promotion of occupational safety & health management systems, which include hazard assessments and identifying safer substitutes
  - California's Safer Consumer Product's Regulation

*Source: Li R, et al. *ACS Nano*. 2013;7(3):2352–2368.

Advancing Alternatives Assessments of Engineered Nanomaterials

1. Start conducting alternative assessments of nanomaterials
   - Pilot studies to inform how to adapt existing hazard assessment tools for nanomaterials
     - AA of nanomaterials for substitution purposes (e.g., MWCNTs as a replacement candidate for flame retardants)
     - AA of nanomaterials to better inform decision decisions (e.g., identify the safest CNT (across the lifecycle) for use in drinking water filters)
2. Adapt existing alternatives assessment frameworks for nanomaterials (e.g., a new module or addendum in the IC2)
   - Include additional relevant physical-chemical hazard indicators
3. Develop protocols for incorporating high throughput screening endpoints into hazard assessment tools
   - Make use of mechanistic endpoints
   - Data availability, need public data repositories of screening data



Available at: www.sustainableproduction.org

"Utility of the Greenscreen® for Safer Chemicals for nanoscale hazard assessment: nanosilver case study"

March, 2014

Jennifer Sass, NRDC
Lauren Heine, Clean Production Action

NRDC NATURAL RESOURCES DEFENSE COUNCIL
THE EARTH'S BEST DEFENSE

CLEAN PRODUCTION ACTION

Goal: Moving to Safer Ingredients and Driving Transparency

In the absence of mandatory product labeling, public debate or laws to ensure their safety, products created using nanotechnology have entered industries, workplaces, and consumer markets.

"We currently know very little about nanoscale materials' effect on human health and the environment. The same properties that make nanomaterials so potentially beneficial in drug delivery and product development are some of the same reasons we need to be cautious about their presence in the environment"

— Linda Birnbaum, Ph.D., director of NIEHS and the NTP

Can We Use the GreenScreen (GS) to Assess Nanomaterials?

Goal - Test the GS as a vehicle to gather and communicate hazard information on nanomaterials

Approach - Convene a prominent group of independent scientific experts to: Define scope of nanomaterials and studies to assess; (size distribution, shape, structure charge, coating, surface chemistry, agglomeration/aggregation, etc); Recommend relevant modifications to the GS method.

Apply the GS to selected nanomaterials (use independent contractor, NSF)

Review results with scientific experts and NGOs

What is the GreenScreen®?

- A method for comparative Chemical Hazard Assessment (CHA) developed by the NGO Clean Production Action
- Allows you to compare chemicals based on hazard in a comprehensive and consistent framework – a level playing field
- Builds on the USEPA DfE approach and other national and international precedents (OECD, GHS)
- Free and publicly accessible, transparent and peer reviewed
- Considers 18 environmental and human health endpoints
- Addresses constituents and breakdown products
- Evaluates hazards for an overall chemical score (Benchmark)

All supporting resources at: http://www.cleanproduction.org/Greenscreen.v1-2.php

GreenScreen Adoption

- Corporate materials selection (HP)
- Corporate policies (Staples)
- State regulations (ME, WA)
- Ecolabels and standards (USGBC LEED v4)
- Alternatives assessments

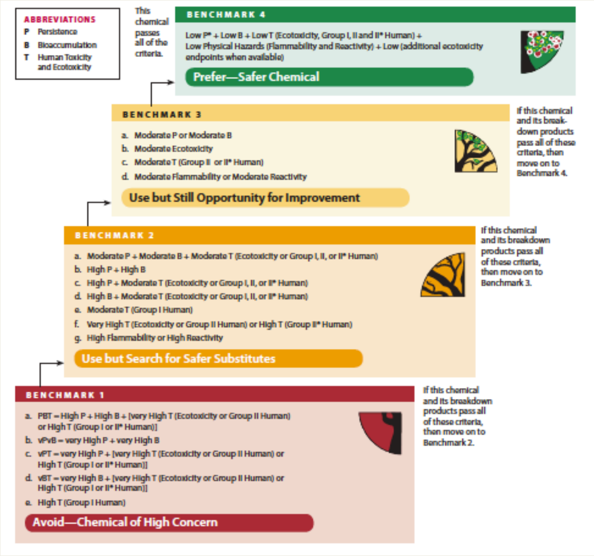
18 Hazard Endpoints

Human Health Group I	Human Health Group II and II*	Environmental Toxicity & Fate	Physical Hazards
Carcinogenicity	Acute Toxicity	Acute Aquatic Toxicity	Reactivity
Mutagenicity & Genotoxicity	Systemic Toxicity & Organ Effects	Chronic Aquatic Toxicity	Flammability
Reproductive Toxicity	Neurotoxicity	Other Ecotoxicity studies when available	
Developmental Toxicity	Skin Sensitization	Persistence	
	Respiratory Sensitization		
Endocrine Activity	Skin Irritation	Bioaccumulation	
	Eye Irritation		

Assign a level of concern for each hazard endpoint e.g. carcinogenicity (H, M or L)

Make Informed Decisions

- Know what you know, and what you don't know
- Benchmarks provide a simple 1-4 score that supports taking action
  - BM1 – avoid/phase out
  - BM2 – manage, to use safely
  - BM3 – getting there
  - BM4 – inherently low hazard



- Can be used by non experts in toxicology to support product design, policies and regulations

Nano Silver

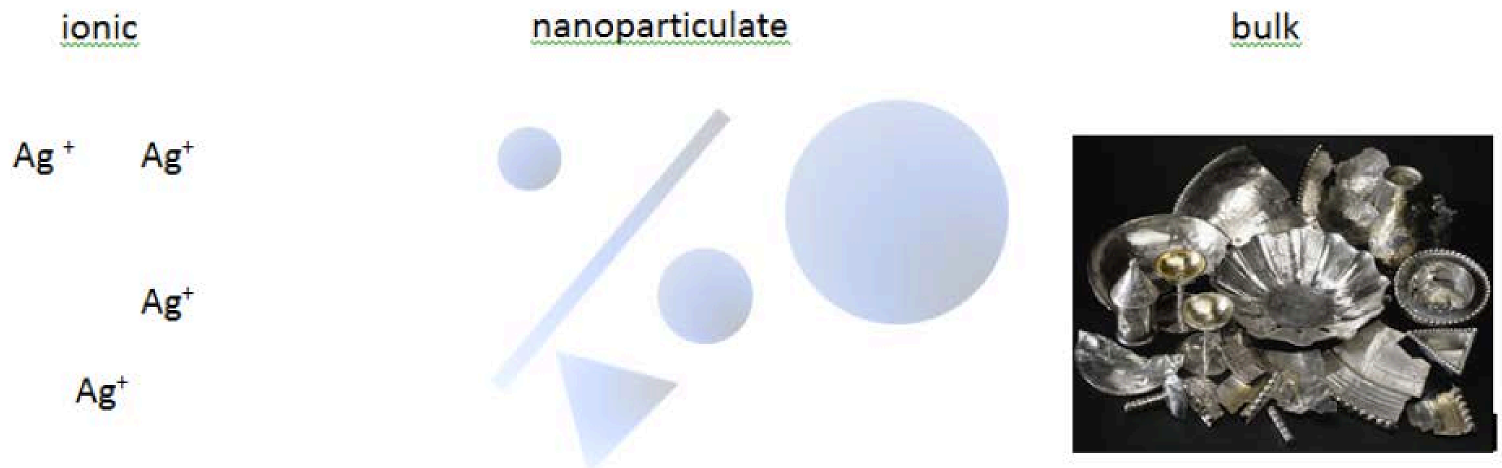


Figure 4. Main differences between ionic, nanoparticulate and bulk silver.

Applications for nanosilver:

- Coatings: for food packaging, food cutting boards, clothing, films, fabrics
- Medical: wound dressing, dental hygiene, and treatment of eye conditions and other infections
- Water treatment processes: surface coatings, including washing machines and paints – leads to significant silver discharge

The specific materials evaluated for this case study were nanoscale metallic silver, a nano silica-silver nanocomposite, and conventional silver (dispersed low-solubility dispersed silver and silver salts).

The extent of nanoscale test material characterization was considered in assessing the adequacy of the studies used.

GreenScreen DRAFT Results - nanosilver

Route	GreenScreen™Hazard Ratings: Dispersed (low-solubility, non-nanoscale) silver - Benchmark Score of 1 based on combined very High Persistence coupled with very High Ecotoxicity, as determined in standardized tests.																			
	Group I Human					Group II and II Human									Ecotox		Fate		Physical	
							ST		N											
	C	M	R	D	E	AT	Single	Repeated	Single	Repeated	SnS	SnR	IrS	IrE	AA	CA	P	B	RX	F
Oral	DG		DG	DG		L	DG	DG	DG	DG										
Dermal	DG	L	DG	DG	DG	L	DG	DG	DG	DG	*L*	DG	L	L	vH	vH	vH	L	L	L
Inhalation	DG		DG	DG		DG	DG	DG	DG	DG										

Route	GreenScreen™Hazard Ratings: Nanosilver, metallic - Benchmark Score of 1 based on very High Persistence coupled with High systemic toxicity and very High Ecotoxicity.																			
	Group I Human					Group II and II Human									Ecotox		Fate		Physical	
							ST		N											
	C	M	R	D	E	AT	Single	Repeated	Single	Repeated	SnS	SnR	IrS	IrE	AA	CA	P	B	RX	F
Oral	DG		DG	DG		L	DG	M	DG	DG										
Dermal	DG	L	DG	DG	DG	L	DG	DG	DG	DG	L	DG	L	L	vH	vH	vH	L	DG	DG
Inhalation	DG		DG	DG		vH	DG	H	DG	DG										

Route	GreenScreen™Hazard Ratings: AGS-20 (silver-silica nanocomposite containing 19.3% silver nanoparticles imbedded in a matrix of amorphous silicon dioxide) - Benchmark Score of U (unspecified) based on numerous datagaps.																			
	Group I Human					Group II and II Human									Ecotox		Fate		Physical	
							ST		N											
	C	M	R	D	E	AT	Single	Repeated	Single	Repeated	SnS	SnR	IrS	IrE	AA	CA	P	B	RX	F
Oral	DG		DG	DG		L	DG	DG	DG	DG										
Dermal	DG	DG	DG	DG	DG	L	DG	DG	DG	DG	L	DG	L	M	DG	DG	vH	DG	*L*	*L*
Inhalation	DG		DG	DG		M	DG	DG	DG	DG										

Summary of DRAFT GS Results

- Both silver (dispersed) and nanoscale (metallic) silver were classified BM1 (highest concern benchmark score)
  - aquatic toxicity, persistence and acute inhalation toxicity
- Silica-nanosilver composite (AGS-20) unassigned (U) due to data gaps

- Acute inhalation hazard – form matters
  - Nanosilver >>Silica-nanosilver composite
- Eye irritation hazard – form matters
  - Silica-nanosilver composite > nanosilver = silver
- Aquatic toxicity – size matters
  - Particle aggregation reduced acute aquatic toxicity

Researchers with the Swedish Chemical Agency tested clothing treated with antimicrobials and measured how much remained in the clothing after three and ten standard washings.

Methods of Silver Incorporation Into Fabrics – not all products are alike

Table 2. Methods of silver incorporation into fabrics ([15], modified).

Method	Silver content (mg/g)
Conventional textile: electrolytically deposited layer of silver (several μm) on fibre	21.6
Plasma-coated fibre with silver nanoparticles (about 100 nm) embedded in polyester matrix	0.39
AgCl (~200 nm) bound to the fibre surface	0.008
AgCl (~200 nm) incorporated in binder on the fibre surface	0.012
Silver nanoparticles bound to the fibre surface	0.029
Silver nanoparticles incorporated into polyester fibre	0.099
Silver nanoparticles incorporated into fibre	0.242
Silver nanoparticles incorporated inside the synthetic fibres (according to manufacturer)	0.003
Nanosized silver incorporated into cotton fibres (according to manufacturer)	2.66

Reidy et al, 2013.

Challenges of Engineering Nanomaterials – What is It, Really?

- Institutes like Safer Nanomaterials and Nanomanufacturing Initiative (SNNI) in Oregon work to develop more benign ways to produce and use nanomaterials because of the challenge of engineering known quantities
  - What is the range of size, shape, etc. produced?
  - Different sizes and shapes can have different toxicities

Principles for the Oversight of Nanotechnologies and Nanomaterials (NanoAction 2007)

1. A precautionary foundation
2. Mandatory nano-specific regulations
3. Health and safety of the public and workers
4. Environmental protection
5. Transparency
6. Public participation
7. Inclusion of broader impacts
8. Manufacturer liability

http://www.centerforfoodsafety.org/files/final-pdf-principles-for-oversight-of-nanotechnologies_80684.pdf

Conclusions

- It is possible to use comparative hazard assessments such as GreenScreen and existing toxicology today – to see what we know and what we do not know (i.e., data gaps)
- Ensure nanomaterials are screened before they are introduced in food & other products:
  - require assessment and public disclosure of results by businesses, NGOs and public sector
  - regulate and require transparency about nanomaterial use in specific products

CORPORATE NANO POLICIES

NIKE sportswear nano policy (2007/2011) . Nike, currently restricts their use “to ensure that any potentially negative impacts to consumers and the environment, associated with the use of nanomaterials, are minimized, if not eliminated”.

GlaxoSmithKline nano policy (2013). Defines nanomaterials and summarizes regulatory positions globally. It confirms using nano TiO2 in sunscreens, and nano in vaccines.

McDonald’s and Kraft have nano policies stating that they do not use nanomaterials in food, packaging, or toys. But, they are researching it for future possible uses.

NO CORPORATE NANO POLICIES, BUT USE NANO

ADIDAS says it only uses the technology "in very single cases," such as its golf shoes coated with a nano-scale polymer waterproof layer

Marks & Spencer (M&S) says it would "only use nanotechnology where there is a proven customer benefit, and where we know it is safe to use. At the moment, it is not in any M&S food or drink products and we only use it in some M&S beauty products, something that is commonplace in the cosmetics industry."

H&M does not use nanosilver in its clothing, but does use nanomaterials in some cosmetic products.

IKEA says it is neutral and flexible.

ACKNOWLEDGEMENT:

We are grateful to CS fund for support to the Coming Clean Collaborative for this project.

We are grateful to NSF International for conducting all DRAFT GreensSreens presented here. These are still in DRAFT phase and may be altered before being finalized.

cs fund

coming clean

Discussion Questions

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Next Webinars

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Alternatives assessment discussion webinars (25 participants)

- **Alternatives assessment in exposure-based safety standards: Are they mutually exclusive?**
  Wednesday, April 16, 12pm est
  Register at: https://www.surveymonkey.com/s/8P652BY

- **Advancing safer flame retardants through informed substitution.**
  Wednesday, April 30, 12pm est
  Register at: https://www.surveymonkey.com/s/8Z9GVZY

- Alternatives assessment and 3-D printing (TBA – May 2014)

Webinar Audio & Slides

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The audio recording and slides shown during this presentation will be available at:

http://www.chemicalspolicy.org/alternativesassessment.webinarseries.php