2013 NNI Stakeholder Perspectives on the Perception, Assessment, and Management of the Potential Risks of Nanotechnology

An NGO perspective

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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

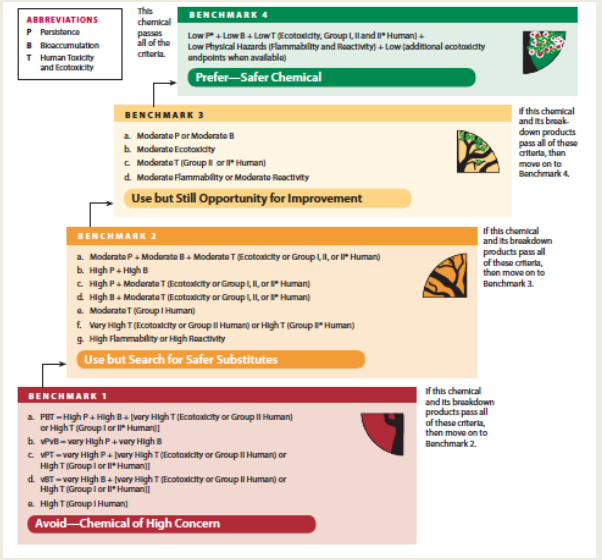
18 Hazard Endpoints

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

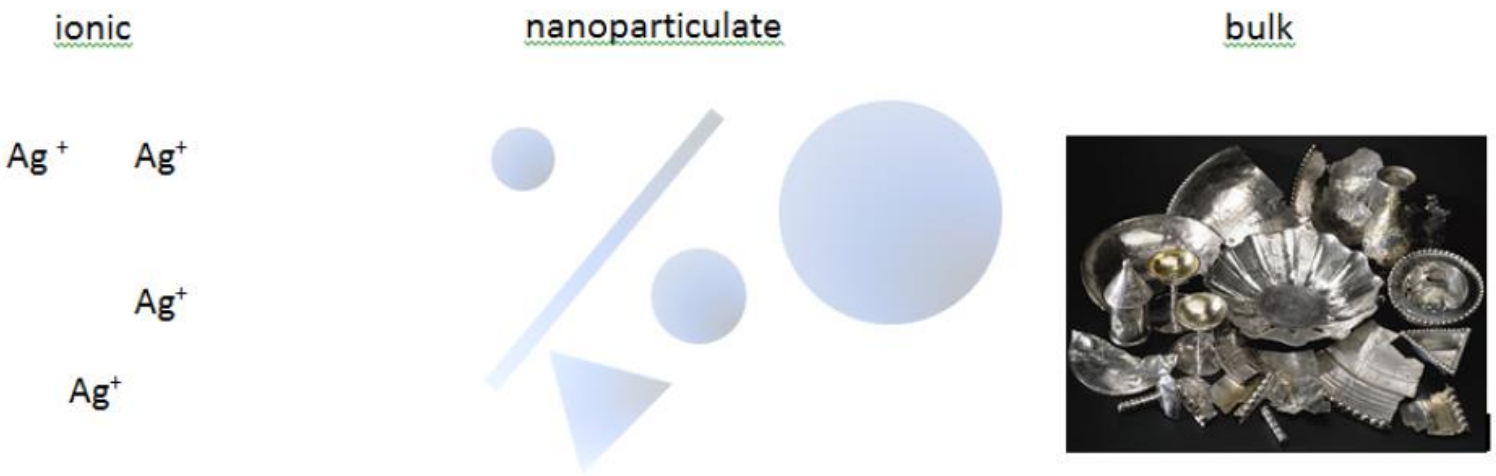
- Know what you know, and what you don't know
- Benchmarks provide a simple 1-4 score that supports taking action
  - BM1 – avoid/phase out
  - BM2 – manage, to use safely
  - BM3 – getting there
  - BM4 – inherently low hazard



- 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 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	
	C	M	R	D	E	AT	ST Single	ST Repeated	N Single	N Repeated	SnS	SnR	IrS	IrE	AA	CA	P	B	RX	F
Oral	DG	L	DG	DG	DG	L	DG	DG	DG	DG	L	DG	L	L	vH	vH	vH	L	L	L
Dermal	DG		DG	DG		L	DG	DG	DG	DG										
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	
	C	M	R	D	E	AT	ST Single	ST Repeated	N Single	N Repeated	SnS	SnR	IrS	IrE	AA	CA	P	B	RX	F
Oral	DG	L	DG	DG	DG	L	DG	M	DG	DG	L	DG	L	L	vH	vH	vH	L	DG	DG
Dermal	DG		DG	DG		L	DG	DG	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	
	C	M	R	D	E	AT	ST Single	ST Repeated	N Single	N Repeated	SnS	SnR	IrS	IrE	AA	CA	P	B	RX	F
Oral	DG	DG	DG	DG	DG	L	DG	DG	DG	DG	L	DG	L	M	DG	DG	vH	DG	L	L
Dermal	DG		DG	DG		L	DG	DG	DG	DG										
Inhalation	DG		DG	DG		M	DG	DG	DG	DG										

Summary of 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

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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.

Fumed Nano Silica

The scope of this GreenScreen is intentionally restricted to use of fumed silica as a flow agent in foods and powders.

Rating[3]: Nano fumed silica was assigned a Benchmark Score of 4 based on low bioavailability, and general lack of toxicity in animal studies and with human experience.

GreenScreen™ Hazard Ratings: Nano fumed silica																	
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
L_o	L	L_o	L_o	L	L_o	L_o	L_o	L_o	L_o	L	L	L	L	L	*L*	vH	L	L	L
L_d		L_d	L_d		L_d	L_d	L_d	L_d	L_d										
L_i		L_i	L_i		Li	L_i	L_i	L_i	L_i										

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance).

Although respirable crystalline silica is a known carcinogen, synthetic fumed amorphous silica is not a listed carcinogen, and the purity of fumed silica is typically high with no contamination by crystalline silica.

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

For details and more information, see Jennifer Sass's blog: *GreenScreen® hazard assessment of silver and nanosilver demonstrates what we know, what we don't, and what we'd like to know before we get too cozy with nanomaterials*. June 11, 2013 Available at: http://switchboard.nrdc.org/blogs/jsass/greenscreen_hazard_assessment.html

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