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This past November we won a lawsuit we'd filed this past January to block a potent antimicrobial nano-pesticide, from market access. The Environmental Protection Agency (EPA) has conditionally registered nanosilver under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use as an antimicrobial in textiles including such things as clothing, baby blankets, and pillow cases. The "conditional" part of the registration means that EPA does not have all the legally required toxicity data, but is letting the pesticide on the market anyway, on the "condition" that the manufacturer, HeiQ, provide it sometime over the next four years.

Silver, a well-recognized antimicrobial, is highly toxic and kills both harmful and beneficial bacteria. Nanosilver is engineered from silver and marketed as an even stronger antimicrobial than silver. Because of its smaller size, nanosilver penetrates organs and tissues in the body that larger forms of silver cannot reach, like the brain, lung, and testes.

In early November, 2013 the Ninth Circuit court ruled in our favor, that the EPA had improperly approved the use of nanosilver by one U.S. textile manufacturer. The court vacated the approval and sent it back to the agency for reevaluation. The key part of the ruling addressed EPA's determination that there is no risk concern for toddlers exposed to nanosilver-treated textiles. The agency's rules state that if there's an aggregate exposure to the skin or through ingestion at or below a specific level, there is a risk of health concerns. But the Ninth Circuit found that the EPA had data showing that nanosilver was right at the level that should have triggered a finding of potential risk, but approved the pesticide anyway. That led to the Ninth Circuit vacating EPA's approval and sending it back down to the agency for reevaluation. (The court decision was reported by a corporate law firm here)

Unfortunately, even before the court finalized its decision, EPA had already proposed to conditionally approve another nanosilver pesticide product, this one called NanoSilva, for textiles and plastics in late August, 2013. Among other things, Nanosilva is proposed to be incorporated into textiles, plastic films, sheets, slabs, and molded parts, meaning it can end up in consumer products such as footwear, sportswear, uniforms, and auto parts, floor coverings, outdoor furniture, decking, and house siding.

And, it's not just pesticides that have gotten "smaller". Under the Toxic Substances Control Act (TSCA) many new nanomaterials have been reviewed and approved for market, all with far less risk assessment data than EPA had for nanosilver. In June 2013 EPA issued significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for chemical substances which were the subject of pre-manufacture notices (PMNs), including carbon nanotubes (CNT), multi-walled carbon nanotubes (MWCNT), double-walled carbon nanotubes (DWCNT), and single-walled carbon nanotubes (SWCNT). NRDC joined with labor unions including AFL-CIO and the United Steelworkers to file comments opposing the proposed rule (Document ID EPA-HQ-OPPT-2010-0279-0130).

In its FR Notice of the proposed rule, EPA identified the following health concerns for the carbon nanotubes: pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity of the PMN substances. There are also data suggesting that pulmonary deposition of some nanoscale materials, including carbon nanotubes in the agglomerated form, may induce cardiovascular toxicity when these nanoscale materials are inhaled. The major health concerns are for potential pulmonary toxicity, fibrosis, and cancer to workers exposed via inhalation. Sublethal effects have been noted for some carbon nanoscale substances in fish at levels as low as 100 parts per billion (ppb). (76 FR 81447). For fullerenes EPA identified that, "based on test data on poorly soluble particulates, including some carbon-based nano-sized chemicals, and test data correlating lung irritation to particle size, EPA has concerns for lung effects from inhalation exposure." Nonetheless, EPA gave its approval despite lacking: in vitro and in vivo mutagenicity testing including genotoxicity and chromosomal aberration tests; acute toxicity including oral, inhalation, and dermal routes of exposure; dermal sensitization and irritation tests; subchronic neurotoxicity tests; chronic tests including oncogenicity, teratogenicity, reproduction toxicity, and developmental toxicity.

Despite the potential risks, the research and development of nanotechnology has skyrocketed in recent years. The independent advisory firm, Research, predicts that in 2015 nanotechnology value chain sales could reach $2.5 trillion. The U.S. government and U.S. corporations spend more money on nanotechnology than any other country, and nanomaterials are found in thousands of everyday products. Russia, the EU and many Asian countries also spend billions each year on new nano chemicals.

The White House is telling the public not to worry, that existing regulatory frameworks are handling these novel nanomaterials adequately.

In contrast, many non-government organizations (NGOs) including NRDC are calling for proper regulatory oversight, and the use of established best practices followed in other chemical handling facilities to protect workers. Without mandatory oversight for the development, use,

and disposal of nanomaterials, companies will remain reluctant to invest resources into new products or technologies without knowing their future regulatory fate or liability risks.

Nanomaterials are pitched as “new and improved” chemicals, engineered at the teeny-tiny “nano” scale (one-thousandth of a micrometer) to be stronger, lighter, faster, brighter, or just plain better than their normal-scale chemical counterparts. And, they are rapidly replacing hazardous chemicals that are being phased out or forced out of consumer products, either through market demands or regulatory restrictions.

But, are we really risk-trading downwards? Or are we just replacing the risks we know about with ones we don’t? A January 2013 report of the National Academies found that, "Despite extensive investment in nanotechnology and increasing commercialization over the last decade, insufficient understanding remains about the environmental, health, and safety aspects of nanomaterials."

The problem is that there are currently no standardized testing protocols, no labeling requirements, and weak regulation of most nanomaterials. And, what we don’t know about the environmental and occupational impacts of nanomaterials may be hurting us. We do not know enough about these materials to make informed decisions about how they should – or should not be used.

This year, 2013, I co-led a project to test the concept that the Greenscreen™ for Safer Chemicals (GS), a comparative chemical hazard assessment framework, could be used to evaluate nanomaterials. Greenscreen™ builds on the U.S. EPA Design for the Environment (DfE) approach, along with the OECD Globally Harmonized System (GHS) and other accepted systems. It is being used by industry, government and NGOs to support product design and development, materials procurement, and as part of alternatives assessment to meet regulatory requirements. It is being used by businesses like Hewlett-Packard, governments, and

NGOs. The Greenscreen™ can also be used to support environmentally preferable product procurement tools including standards, scorecards and ecolabels.

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		

In a Greenscreen™, chemicals are assessed according to eighteen hazard endpoints (including chronic and acute toxicity, ecotoxicity, and physical characteristics such as flammability and reactivity), scored for each endpoint according to the available data or lack thereof (i.e. a data gap), and then assigned a Benchmark score (BM) from 1 to 4, with 1 being the most hazardous. Where there are no data for an endpoint, Greenscreen™ can use analogs, modeled data, or other available reasonable substitutes to inform that endpoint. Confidence in the score is identified as high (a bold letter), low (an italics), or very poor (DG, data gap). Chemicals that are carcinogens, mutagens, reproductive and/or developmental toxicants, endocrine disruptors, and PBTs (persistent, bioaccumulative, and toxic) would be considered substances of high concern, with a BM 1.

For silver, the specific materials evaluated for this case study were nanoscale metallic silver, a silica-silver nanocomposite, and conventional low-solubility dispersed silver and silver salts. Both silver and nanoscale silver scored a benchmark of high concern, based on high aquatic toxicity, high persistence (long-lasting in the environment), and acute inhalation toxicity concerns. The identified data gaps include: reactivity, flammability, carcinogenicity,

reproductive toxicity, and endocrine disruption. The silica-nanosilver composite, a form recently conditionally approved by EPA for use in textiles as an antimicrobial agent, was unassigned (BM Unspecified (U)) due to several data gaps. U.S. EPA approved the composite (AGS-20) for textiles in 2011, based in part on the assumption that toxicity is governed by Ag+ ions, thus silver nitrate and other soluble salts could be used as analogs to fill data gaps. Our GS assessment did not use silver nitrate or other soluble silver salts as analogs to fill data gaps, because the point of the screen was to examine particle size-specific hazards.

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	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	
							ST		N											
	C	M	R	D	E	AT	Single	Repeated	Single	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	
							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	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										

Some of the challenges and limitations for the GS when assessing nanomaterials include: each nanomaterial may be comprised of different substances and exist in different forms, whereas conventional chemicals are a single entity with a unique CAS#; it's unclear whether data from standardized test protocols are always appropriate for nanomaterials; the "dose-response" for

nanomaterials may be better reflected by alternative metrics, such as surface area or particle number, rather than by mass; the current state of knowledge of nanomaterial toxicology is too limited to reliably use analogs and predictive models to fill data gaps. This is an area of active research, and given the limitations and challenges for this evaluation, it is likely that future evaluations may yield different results.

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