

Consumer Exposure

QEENI: Summary and Needs Progress

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These comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

Outline

- CPSC Interagency work and Contracts
- QEENI Highlights and Needs

Federal and International Collaborations

- DOD, EPA, FDA, NIOSH, NIST, NLM, NNCO, NSF
- NanoWIR²ES, University of Florida (Chris Volpe): NanoWire intelligent re-design and recycling for environmental safety
 - International project under the Safe Implementation of Innovative Nanoscience & Nanotechnology (SIINN) program
- Rutgers University (Gedi Mainelis): Risk Assessment for Manufactured Nanoparticles Used in Consumer Products (RAMNUC)



Federal Collaborations

- EPA (Todd Luxton): work assessed the release of CuNPs from micronized copper treated lumber; current work is evaluating ENM surface coatings applied to indoor and outdoor surfaces, metal oxides (zinc, cerium)
- DOD (Igor Linkov, Al Kennedy, Taylor Rycroft): Nanoprioritization tool



Framework and pilot tool for the risk-based prioritization of nano-enabled consumer products

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Rycroft, T., Larkin, S., Ganin, A., Thomas, T., Matheson, J., Van Grack, T., Chen, X., Plourde, K., Kennedy, A., Linkov, I. (submitted). A Framework and Pilot Tool for the Risk-based Prioritization of Nano-enabled Consumer Products. Environmental Science: Nano.

ERDC
Engineer Research and Development Center

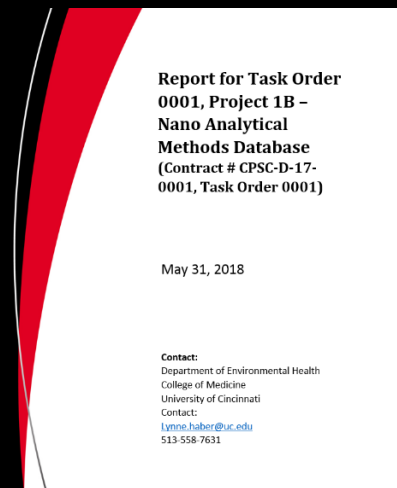
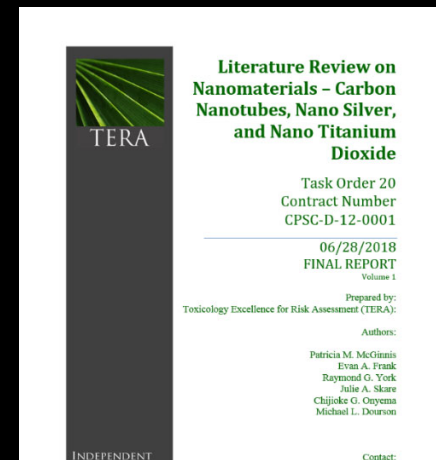
US Army Corps of Engineers

U.S. ARMY

Innovative solutions for a safer, better world

Toxicology Contracts

- TERA (Pat McGinnis): Literature review on nano silver, carbon nanotubes, and nano titanium dioxide
- University of Cincinnati (Jacqueline Patterson, Lynne Haber):
 - Commercialization report
 - Nanomaterials hazard and properties database
 - Update the TERA literature review report and develop dose metrics
 - Literature review on nano aluminum, nano cellulose, nano silica, and graphene toxicity



Nanomaterial Hazard Data by Route of Exposure

Material	Route	Fields																		
		Will the NM change form in the body?	Is the NM biopersistent?	NM Classified by Relevant Authority (GHS, HCS)	NM Carcinogenic	NM Neurotoxic	NM a Dermal hazard (SEN, SYS, IRR, COR)	NM an Asthmagen	NM Acutely Toxic	NM Hepatotoxicity	NM Nephrotoxic	NM Immunotoxic	NM a Blood / Hematopoietic Hazard	NM a Pulmonary Hazard	NM an Ocular Hazard	NM Genotoxic	NM Hazardous to Another Organ	NM a Cardiovascular Hazard	NM a Developmental Hazard	NM a Reproductive Hazard
MWCNT	O	U	U	ND	U	ND	N	ND	N	M	U	ND	U	U	Y	U	Y	ND	N	U
	I	Y	Y	ND	Y	U	U	M	N	Y	Y	Y	ND	Y	Y	Y	ND	ND	ND	U
	D	ND	ND	ND	ND	U	M	ND	N	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Nano silver	O	ND	Y	ND	ND	Y	N	ND	N	Y	Y	Y	Y	U	U	Y	Y	U	Y	Y
	I	ND	ND	ND	ND	Y	N	ND	Y	Y	U	Y	Y	Y	U	U	ND	U	ND	U
SWCNT	O	ND	ND	ND	ND	ND	N	ND	N	U	U	Y	U	ND	N	Y	U	ND	Y/N	ND
	I	ND	Y	ND	ND	ND	N	ND	ND	ND	ND	Y	U	Y	Y	Y	U	U	ND	ND
	D	ND	ND	ND	ND	ND	N	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Nano titanium dioxide	O	Y	ND	ND	U	Y	ND	ND	ND	Y	Y	Y	Y	ND	N	Y	Y	Y	Y	Y
	I	Y	Y	ND	Y	ND	Y	ND	ND	ND	ND	Y	U	Y	Y	Y	ND	Y	Y	ND
Nano titanium dioxide	D	ND	ND	ND	ND	ND	N	ND	U	Y	ND	Y	ND	ND	ND	ND	ND	ND	ND	ND

ND = no data; U = unknown; Y = yes; M = mixed; N = no; SEN = sensitizer; SYS = systemic toxicity; IRR = irritation; COR = corrosive; O = oral; I = inhalation; D = dermal

Communication

- CPSC Chemical Hazards webpage: <https://www.cpsc.gov/Research--Statistics/Chemicals>

Quantifying Exposure to Engineered Nanomaterials (QEEN) from Manufactured Products
Addressing Environmental, Health, and Safety Implications

Workshop Proceedings
July 7–8, 2015

Sponsored by the
Consumer Product Safety Commission
in collaboration with the
National Nanotechnology Initiative

$$\text{Exposure} = f(\text{Concentration}) \times (\text{Exposure Factors}) dt$$

Substance fate and transport

Substance matrix interactions

Population characteristics

Population behavior

Integrated over time

QEENI Summary

- Significant progress made in the development of characterization tools and techniques, exposure assessment methodologies, simulation and modeling tools, to quantify ENM exposures
- Science-based estimate of risk requires knowledge of realistic exposure scenarios and the actual released materials to which exposure may occur

QEENI Summary: Consumers

- What is released from nano-enabled products is often a mixture of ENMs and other product ingredients, product matrix likely affects ENM emissions
- ENM release levels are expected to be low and exposure scenarios are likely to be chronic
- Systemic consumer exposure to ENMs is dependent on ENMs ability to translocate; translocation is slow so exposure is anticipated to be low over a product's lifetime
- Children have higher exposures per unit body mass to AgNPs in consumer products

Needs – Realistic Exposure

- Realistic exposure assessment is challenging – consider the entire life cycle of products and their individual usage scenarios
 - Zebrafish embryo toxicity to sock-AgNPs
 - Requires a tiered approach – evaluate material hazards, exposure potential and toxicity to determine initial risk
 - Characterize intact products & ENM within
 - Realistic exposure scenarios, foreseeable misuse
 - UV degradation, leaching (biological fluids, food), temperature, mechanical stress

Needs – Realistic Exposure

- Use-specific bioavailability studies to understand potential for consumer exposure
 - NanoAg-enabled medical garment, assessed “in use” exposure to Ag at different depths of the stratum corneum
- Distinguishing between naturally occurring or incidental NMs and ENMs of interest
- More studies on complex, realistic matrices and exposure scenarios (e.g., milk vs. diH₂O)

Needs – Post Exposure

- Lack of data on NM biodistribution, bioavailability, biotransformation, bioaccumulation or adverse outcomes in humans from NMs released from consumer products
 - Distinguish exogenous NMs from normal tissues and localization of sparsely distributed materials
- Evaluation of *in vivo* transformations and subsequent toxic effects resulting from realistic conditions

Needs - General

- Lack of epidemiological studies, all workplace
- Determining biomarkers of exposure linked to disease
- Routes of exposure: ingestion studies
- More relevant metrics indicative of exposure risk (as opposed to mass)

Needs: Quality Control

- Establish consumer product specific QA/QC safeguards to minimize errors, losses and uncertainties - more benign sample preparation methods as well as *in situ* methods for physico-chemical property characterization
- Collection and analysis introduce opportunities for NM loss
 - Performing mass balance is key step in exposure studies

Needs: by Media or Pathway (Aerosols)

- Quantification of airborne ENMs should consider characterization, source and physical and chemical stability of an aerosol with time, account for background exposure levels
- Development of standard methods for characterizing emissions from groups of consumer products (i.e., sprays, powders, paints), not only in terms of aerosol size distribution, but also in terms of shape, chemical composition, crystallinity.
- Studies to determine how these characteristics relate to potential toxicity and how the matrices affect aerosol release.

Needs

- While electron microscopy has been the gold standard, no methods to answer the question: How many NMs are in a product (when a manufacturer has not indicated)

Needs

- Continual conversation between the exposure science and toxicology communities to determine appropriate ENM doses, purity levels, and matrices for toxicology studies; to ensure data generated from release studies is transferable and useful to subsequent studies.
- Develop guidelines on the design and implementation of exposure studies: to ensure repeatability of studies, data sharing

Needs

- Developing standards and generalized release scenarios will help move the field forward – the wide variety of NMs makes generalization a challenge
 - Voluntary standard organizations activities (ASTM, ISO)