Day 1

Welcome

Treye Thomas *(CPSC), Environmental, Health, and Safety Coordinator, National Nanotechnology Initiative (NNI)*

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Day 1 AM Plenary Talks

Advances and Knowledge Gains since QEEN I: ***Charles (Chuck) Geraci*** (NIOSH)

What Have We Learned About Environmental Realism with Respect to Nanomaterial Exposure? ***Paul Westerhoff*** *(Arizona State U.)*

Concurrent Breakout Session 1A. Quantifying Potential Acute and Chronic Exposure from 3D Printing/Additive Manufacturing

Co-chairs: Tim Nurkiewicz (West Virginia U) and Alyson Johnson (NIOSH)

3D printing processes generate complex emissions that are dependent on printing format, consumables and environmental conditions. Human inhalation exposure to similarly sized particulates is known to cause adverse cardiopulmonary outcomes. The current challenge for health assessment is proper quantification of the risk and safe exposure limits. The purpose of this session will be to cover the factors influencing emissions from 3D printing equipment, exposure assessment strategies, and associated health outcomes.

Speakers*:* ***Peter Byrley*** *(EPA);* ***Justin Gorham*** *(NIST);* ***Sandra Pirela*** *(SafeBridge Consultants, Inc.);* ***Souhail al-Abed*** *(EPA)*

Concurrent Breakout Session 1B. Assessing Exposure and Health Effects for Nanomaterial Workers: Epidemiologic and Biomarker Approaches

Co-chairs: Paul Schulte (NIOSH) and Gabriele Windgasse (CA Dept. Public Health)

In this session, the issues and methods for epidemiological study of nanomaterial workers will be discussed. These studies generally have focused on biomarkers of exposure and effect, and we will address the use and interpretation of these biomarkers. Examples of existing worker registries and epidemiological studies will be reviewed. In addition, we will discuss the relevance of air pollution studies of ultrafine particles and attempt to identify elements for best practices to protect public health.

Speakers Paul Schulte *(NIOSH);* ***John Beard (****Brigham Young University****);* ***Robin Keeler*** *(Department of Energy);* ***Mike Kleeman*** *(UC Davis);* ***Gabriele Windgasse*** *(CA Dept. Public Health)*

Concurrent Breakout Session 1C. Integrating Exposure and Toxicity Assessments of Nanomaterials at Different Stages of the Life Cycle

Co-Chairs: Aaron Erdely (NIOSH) and Christie Sayes (Baylor U.)

Toxicity of engineered nanomaterials initially focused on as-produced (pristine) materials with little attention to downstream applications or guidance from detailed exposure assessment. Given the broad applications of nanomaterials into existing and emerging technologies, a more expansive characterization of exposure was needed to understand potential health risks. Understanding the changing exposure profile of engineered nanomaterials along the life cycle, which increases in complexity from the pristine material to product incorporation and environmental accumulation, is critical for overcoming risk-driven concerns that are potential barriers to increased commercialization. The comprehensive approach of using detailed exposure assessments to design and interpret toxicity studies is necessary to provide direct inference to potential human health risks. This session will update the state of the science of occupational, consumer, and environmental exposure-driven toxicity assessments and compare the properties of pristine materials against transformed materials of varying complexity.

Speakers: ***Kim Rogers*** *(EPA);* ***Aaron Erdely*** *(NIOSH);* ***Mark Wiesner*** *(Duke U.);* ***Jenny Roberts*** *(NIOSH);* ***Christie Sayes*** *(Baylor U.)*

Concurrent Breakout Session 1D. Exposure to Nanomaterials in Agroecosystems and Agricultural Production

Co-chairs: Jason White (Connecticut Ag. Expt. Sta.) and Arturo Keller (UCSB BrenSchool)

There are several potential human exposure pathways associated with nanomaterial use in agricultural production and farming landscapes. This session describes some of the potential applications of nanomaterials in agroecosystems, as well as current knowledge on the characteristics, levels of exposure, and potential implications for agricultural environments and human food supply chain.

Speakers: *Greg Lowry (Carnegie Mellon U)*[1]*;* ***Juan Pablo Giraldo*** *(UC Riverside);* ***Swadeshmukul Santra*** (U. Central Florida); **Mathews Paret** (U. of Florida); ***Carmen Gomes*** *(Iowa State);* ***Wade Elmer*** *(Connecticut Ag. Exper. Sta.);* ***Leanne Gilbertson*** *(U. Pittsburgh)*

Day 1 PM Plenary Roundtable: Connecting the Pieces-Linking Manufacture and Use of Nanomaterials or Nano-enabled Products with Exposure, Outcome, and Risk

Chair: Igor Linkov (U.S. Army ERDC)

Even though a great deal of information on nanomaterials (NMs) exposure and toxicity have been collected, these data are rarely used in designing safe products. This roundtable will use a case study approach to present the challenge and elicit vision from manufacturers, regulators, and academia on implementing safety-by-design and risk governance. The case study will discuss a specific product and the potential risks associated with its current use. Panelists will be asked to comment on ways to implement safety by design for this case-study product.

Panelists: ***Benjamin Trump*** *(U.S. Army ERDC);* ***Mark Wiesner*** *(Duke U.);* ***Wu-Sheng Shih*** *(Brewer Science);* ***Will Boyes*** *(EPA)*

[1] Via remote connection

Concurrent Breakout Session 2A. Exposure Scenario: Workplace Exposure

Co-chairs: Laura Hodson (NIOSH) and Scott Brown (Chemours)

Significant progress has been made in the occupational exposure assessment and monitoring of nano-objects. Improvements in assessment protocols, broader availability of suitable low-cost methods, and international standards activities have made strides in our understanding of exposure incidence, exposed form, and effective engineering controls, as well as current gaps and future opportunities. Advances have been made in quantifying and characterizing nanomaterials in complex dust streams, although some challenges remain; perspectives on approaches to closing these gaps will be given. Communication and knowledge transfer to secondary manufacturers and downstream users remains an area for improvement. Improved methods for predicting the exposure potential of a nanomaterial—and particles in generals—remains a challenge. Progress and barriers towards the harmonization of approaches to predict workplace exposure will be discussed.

Speakers*: **Kevin L Dunn** (NIOSH); **Delphine Bard** (HSE); **Michele Shepard** (Colden Corp.); **Marilyn Black** (UL)*

Concurrent Breakout Session 2B. Exposure Scenario: Consumer Exposure (General Products)

Co-chairs: Joanna Matheson (CPSC) and Sandra Pirela (*SafeBridge Consultants, Inc.*)

Progress on the assessment of consumer exposures to nanoparticles released from nano-enabled products will be discussed. In particular, presentations and discussions will focus on collaborative work in characterizing the airborne release of—and potential exposure to—nanoparticles from nano-enabled cleaning sprays, textiles, and printing equipment. Further, speakers will present data on the physicochemical characterization of the emissions, describe the currently available prioritization and predictive models, as well as current studies on assessing exposure via multiple routes of exposure, including those due to resuspension of deposited particles.

Speakers: ***Gedi Mainelis*** *(Rutgers U.);* ***Sandra Pirela*** *(SafeBridge Consultants, Inc.)****; Joanna Matheson*** *(CPSC)*

Concurrent Breakout Session 2C. Nanomaterial Exposure in Ecological Systems

Co-chairs: Elijah Petersen (NIST) and Monika Mortimer (UCSB)

This session will focus on quantifying nanomaterials both in the exposure media (soil, sediment, or aqueous media) and in organisms. For measurements in organisms, there may be direct measurements of the engineered nanomaterial (ENM) in the organism and potentially indirect measurements if changes in biomarkers are correlated to a concentration of the ENM in the organism.

Speakers: ***Paul Westerhoff*** *(Arizona State U.);* ***Adeyemi Adelaye*** *(UC Irvine);* ***Monique Johnson*** *(NIST);* ***Elijah Petersen*** *(NIST);* ***Monika Mortimer*** *(UCSB)*

Concurrent Breakout Session 2D. Emerging Technologies and Advanced Materials: Industry Perspectives on Exposure, Hazard and Risk Assessment

Co-chairs: Shaun Clancy and Silvia Maberti (Exxon Mobil)

As the use of advanced materials in industrial and consumer applications continues to increase, concerns have arisen regarding potential health effects of exposures to untested materials, which

are not disclosed in safety data sheets. Because of this, exposure to nanomaterials is becoming one of the most significant and misunderstood risks in the workplace, especially in the secondary industry (industrial or professional users of nano-enabled materials). Recognition and assessment of exposure to nanomaterials in workplaces where they are being used (rather than where they are manufactured) is limited due to the lack of information on and understanding of the relationships between the nanomaterial parameters and their toxicological effects, and lack of field-tested sampling methodologies that allow their assessment. Challenges include the fact that currently available methods for assessment of exposure do not take into consideration toxicity of the nanoparticles or their agglomerated forms. This session will address how different stakeholders (industry, Federal regulators, and oversight agencies) are dealing with real-world challenges in assessing exposure and therefore in mitigating risk for emerging and advanced materials.

Speakers*: Bruce Lippy* *(CPWR);* ***Angela Hight Walker*** *(NIST);* ***Rick Canady*** *(Neutral Science)*

Ken Moss *(EPA*); ***Treye Thomas*** *(CPSC)*

Day 1 Closing Plenary

Chair: Deborah Burgin (CDC ATSDR)

Reporting on key takeaways from the concurrent sessions and roundtable

Day 2

Day 2 AM Plenary Talk and Roundtable: Are Poorly Soluble, Low-Toxicity Particles a Model for Nanomaterial Inhalation Exposure and Risk Assessment?

Chair and Moderator: Will Boyes (EPA)

Exposure to nanomaterials typically occurs not to pristine particles, but to particles as a component of a complex mixture of natural and synthetic materials. Nanomaterials can be transformed through their interactions with physical and biological environments. The safety assessment of highly purified and nanomaterials may not represent the potential risks of real-world exposures. This session will use cases studies to illustrate the importance of considering exposure factors as a primary component of designing and interpreting nanosafety evaluations

Exposure driven risk assessment of engineered nanomaterials released from nano-enabled products across their life cycle: Lessos learned from case studies. ***Phil Demokritou*** *(Harvard TH Chan School Public Health)*

Panelists: *Gedi Mainelis* *(Rutgers U.);* ***Alison Elde****r (U. of Rochester)*

Concurrent Breakout Session 3A. *Dosimetry Modeling and Computational Approaches to Evidence Integration*

Chair: Annie Jarabek (EPA)

Data evaluation and testing approaches to support a broad range of regulatory applications, ranging from screening or prioritization to quantitative risk assessment for registration, requires integration of available evidence on potential toxicity. Such evidence may include epidemiological studies, *in vivo* laboratory animal data, and increasingly *in vitro* or *in silico* approaches. Alignment of exposures through careful characterization of target site exposure across these studies will ensure that the evidence is properly integrated. This session will examine the various parameters, both physicochemical and physiological, that are determinants of internal exposure and resultant toxicity

for nanomaterials. We will explore how these test systems and studies can provide mechanistic information to support the understanding of nanomaterials within the larger context of particles and fibers. For example, we will address questions such as "What physicochemical properties or physiological factors determine aerodynamic delivery or toxic response(s)?"; "What is the role of exposure duration in response?"; "What is the appropriate dose metric?" and "How are doses translated across experimental design?" Reporting standards and ontologies to advance a common understanding of nanomaterial toxicity will also be discussed.

Speaker: *Holger Behrsing* *(Institute for In Vitro Sciences Inc.);* ***Christine Hendren*** *(Duke U.);* ***Jordan Smith*** (Pacific Northwest National Lab); **Gunther Oberdoerster** (U. of Rochester);

Concurrent Breakout Session 3B. Consumer Exposure: Food and Food Contact and Personal Care Products

Co-chairs: Hongda Chen (NIFA) and Jo Anne Shatkin (Vireo Advisors)

This session will articulate the relevance and the scale of impact of various engineered nanomaterials in food, food contact, and consumer products, either as functional additives or as the resultants of processes. The session will focus on the status of efforts to quantify human exposure to engineered nanomaterials in food-related applications (food and food contact) as well as personal care products. It will update the recent knowledge about gastro-intestinal tract (GIT) uptake and biodistributions of engineered nanoparticles in food and food contact materials. Speakers will offer brief perspectives on current developments, presenting new measurement methods and data sets as well as outstanding questions and challenges. A panel discussion will follow to identify challenges and opportunities to advance the science and address remaining knowledge gaps.

Speakers: ***Hang Xiao*** *(U. of Mass. Amherst);* ***Cristina Sabliov*** *(Louisiana State U);* ***Tim Duncan*** *(FDA);* ***Yanyun Zhao*** *(Oregon State U.);* ***Maria Rubino*** *(Michigan State U. School of Packaging)*

Concurrent Breakout Session 3C. Characterization and Quantification

Co-chairs: Todd Luxton (EPA) and Keana Scott (NIST)

The session will focus on current and emerging methods for characterizing and quantifying nanomaterials under various exposure scenarios. Quantifying and characterizing ENMs throughout the product/material life cycle are complicated by physicochemical properties, ENM-matrix interactions, and material use conditions. This, in turn, impacts the downstream transformation, degradation/decomposition route, and release potential of ENMs. Presentations will emphasize how a variety of analytical techniques can be used to overcome these challenges to accurately assess availability and exposure.

Speakers: ***Kirk Scheckel*** *(EPA);* ***James Ranville*** *(Co. School Mines);* ***Justin Clar*** *(Elon U);* ***Ryan Beams*** *(FDA);* ***Jason Unrine*** *(U. Kentucky);* **Jana Navratilova** *(EPA);* ***Matt Bangert*** *(NanoComptech Technologies)*

Concurrent Breakout Session 3D. Meet the New Investigators: Fresh Perspectives on the Breakthroughs They are they Hoping to Make and the Challenges They Face

Co-chairs: Dilpreet Singh (Harvard TS Chan Sch. Public Health) and Lisa Friedersdorf (Director, NNCO)

Speakers: ***Nancy Monteiro-Riviere*** *(Kansas State U.);* ***Zach Sheppard*** *(U. Rhode Island****); Lila Thornton*** *(Duke U. and Young Nanoscientists);* ***Kevin L. Dunn*** *(NIOSH);* ***Scott Brown*** *(Chemours)*

The purpose of this breakout session is to introduce new investigators to the community of nanomaterials EHS scientists, to highlight fresh perspectives and approaches being advanced by them, and to foster communication between new and senior investigators from diverse sectors (academia, industry, government). This breakout session will be an informal Q&A with the moderators, investigators (new and senior), and breakout session registrants.

Day 2 PM Plenary Talk and Roundtable: Fostering U.S. -International Collaboration in Integrating Exposure in Nanomaterial Risk Evaluation

Chair: Janet Carter (OSHA)

Introduction of nanomaterials into commerce coincided with a societal shift from reactive to proactive risk assessment and mitigation. The nature of nanomaterials and the new paradigm for managing risks of emerging technologies in society brought about several challenges and opportunities for exposure assessment of nanomaterials. Specifically, the chemical and particulate properties of nanomaterials demand new characterization and measurement tools and close research collaborations across a wide range of scientific disciplines, while additional flexibility in nanomaterial form and composition provides opportunities to minimize exposures through material and process design. The proactive approach to risk management allows evaluation and mitigation of exposures to nanomaterials throughout the life cycle stages of nanomaterials before adverse effects take place, while posing challenges of doing this in the absence of well-established tools for exposure characterization of nanomaterials. These opportunities can be best realized and challenges can be best addressed if there is effective coordination of activities among all stakeholders on a global scale.

Coordination can be realized at several levels (see Figure 1): (1) communication of exposure and risk assessment needs from public organizations to researchers and of newly generated knowledge from researchers to public organizations; (2) coordination of programs among public organizations on a bilateral basis (e.g., Canada-U.S. Regulatory Cooperation Council) and on a multilateral basis (e.g., United Nations, OECD); (3) coordination among researchers (e.g., U.S.-E.U. Communities of Research on nanoEHS); (4) coordination of exposure-related activities among public and private international organizations (e.g., liaison between OECD WPMN and ISO TC229); (5) participation of researchers in the standards development activities of public and private international organizations. How can coordination at each of these levels be further improved?

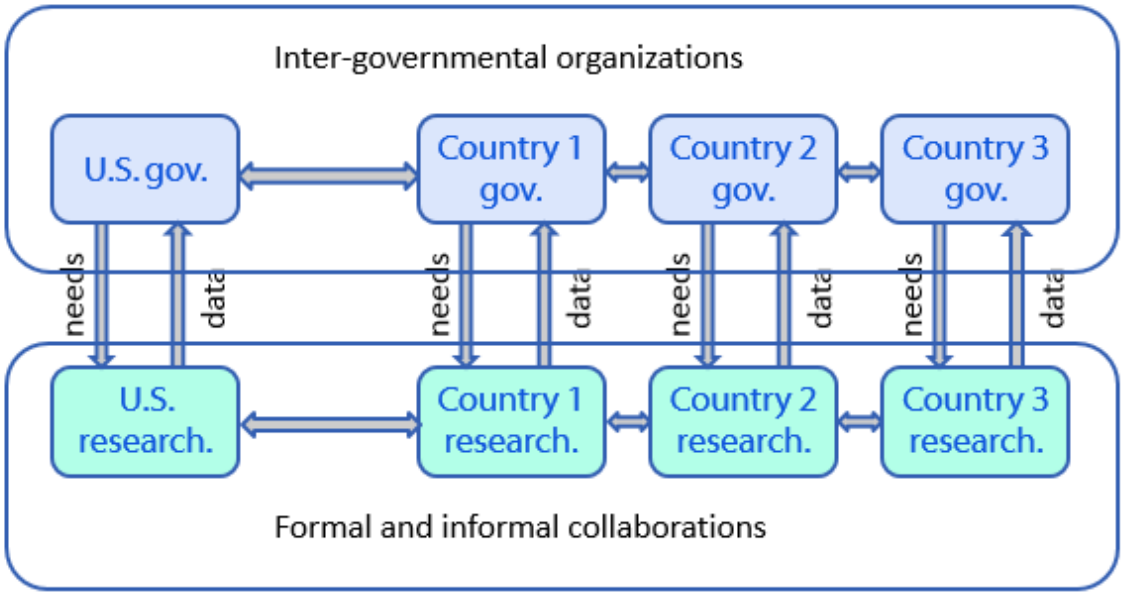

Figure 1. Collaborations on nanomaterial exposure

Plenary speaker: *Vladimir Murashov* *(NIOSH)*

Panel: *Anil Patri* *(FDA);* ***Rick Canady (****Neutral Science****); Nora Savage (****NSF****); Christof Asbach*** *(IUTA)****; Cathy Fehrenbacher*** *(EPA)*

Workshop Wrap up